

eClinical 2.0: Turning the Vision into Reality

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The first generation of eClinical technologies, such as Electronic Data Collection (EDC), Interactive Voice Response Systems (IVRS) and Clinical Trial Management Systems (CTMS), has been in use for a number of years; in some cases, a decade or more. These technological advances have helped the pharmaceutical industry realize significant improvements in efficiency and data quality in clinical trials and other aspects of drug development. Despite the important benefits delivered by eClinical systems, however, the industry continues to be relatively slow in embracing new technologies. As a result, the rate of technological advancement for clinical trials has not kept pace with the radical changes that have swept through the industry in recent years.

Faced with intense marketplace pressure to bring innovative compounds to market more quickly, as well as demands from regulatory agencies and the public to improve drug safety, trial sponsors must implement equally radical changes if they are to compete successfully in this new environment. The next generation of eClinical technologies (sometimes referred to eClinical 2.0) holds the potential to help the pharmaceutical industry overcome these daunting challenges by dramatically improving data access and integration throughout the drug development process. Access to more comprehensive, integrated trial information will allow sponsors to make better development decisions, increase patient safety, and reduce time to market.

While these new technologies pose their own challenges, especially in the area of data standardization and interchangeability, the changing requirements of global markets and regulators make the implementation of eClinical 2.0 systems absolutely vital. By understanding the forces driving the market and leveraging the right technologies, the pharmaceutical industry can turn the eClinical 2.0 vision (ie, greater strategic access to integrated, comprehensive trial data) into a reality that supports new levels of performance and meets the demands of a rapidly evolving marketplace.

The changing pharmaceutical environment

There are two key forces in the pharmaceutical environment driving the need for radical changes in drug development processes: competitive marketplace pressures, and refocused regulatory priorities.

Marketplace pressures

Several major changes have occurred in the pharmaceutical marketplace in recent years that have fundamentally altered the competitive landscape of drug development:

- Patents have expired for a significant number of blockbuster drugs, with most losing a substantial percentage of their market share to generics. This phenomenon is creating pressure on pharmaceutical companies to quickly develop and introduce new products to replace them.
- Fewer drugs currently in development have the potential to become blockbusters, so a greater number of 'smaller' drugs must be developed. As a result, pharmaceutical companies must conduct a greater number of clinical trials, at a time when the cost of trials is skyrocketing.
- The diseases being targeted, and the treatments for them, are increasingly complex, creating higher development costs. This is especially true for the growing number of biopharmaceutical and genetic therapies.
- Growing global competition, combined with the above factors, is creating tremendous pressure within the pharmaceutical industry to control costs and increase the efficiency of drug development.

Regulatory pressures

As a result of several widely-publicized incidents involving marketed pharmaceuticals, the issues of patient safety, adverse events, and failed efficacy are at the forefront of regulatory (and public) attention. Regulatory agencies in North America and Europe are promulgating stricter regulations for all phases of clinical development that could lead to larger trials, requirements for additional safety data, and increased post-marketing monitoring; all of

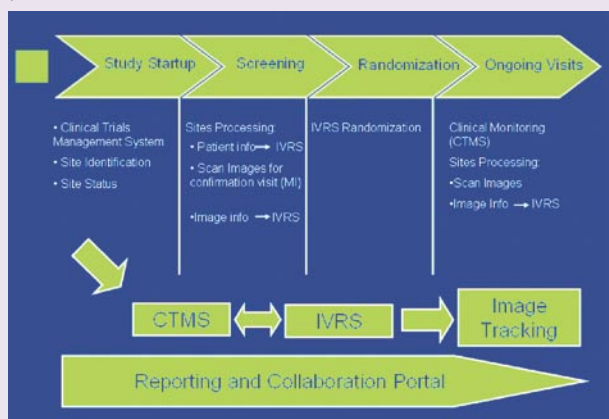
The key attributes of eClinical 2.0 solutions

What does the pharmaceutical industry need to look for when evaluating eClinical 2.0 solutions? At the top of the list would be interchangeability and interconnectivity of data between standard components in the clinical environment, such as CTMS, IVRS, and EDC. Trial sponsors need integrated data systems that work together seamlessly and eliminate multiple points of data entry and re-entry, as well as easier data transfer between systems. The ability to bring the data together from the various development processes to create a broader picture of a compound's characteristics is paramount to improving quality, safety, and decision-making.

Customer case study

The following diagram describes the data transfer between a Clinical Trial Management System (CTMS), Interactive Voice Response System (IVRS), and portal, incorporating Medical Imaging (MI) information, as required by the study protocol. For this protocol, the Medical Imaging system will collect from an MRI the volume of a particular organ for patient inclusion in the study.

Overall, the portal will be the primary communication mechanism to the study team, for status and metrics across systems, providing business intelligence at any point during the study.



As sites are identified and become approved, this site information will be passed from the CTMS to the IVRS system, thus pre-populating the IVRS system. Patient information will be collected in the IVRS, and then the patient data will be transferred to the CTMS.

Site information will also be automatically transferred to the Medical Imaging system. Patients will be evaluated at the screening visit, with MRI measured organ volume being entered into the IVRS system for patient inclusion. Randomization processing also occurs in the IVRS.

This automated data transfer is expedient and efficient, eliminating additional manual site and patient data entry steps, and also ensures higher data quality, minimizing conflicts due to disparate human entry.

Comprehensive, integrated data is especially important in the area of drug safety. The ability to quickly integrate and analyze safety data from all sources at the earliest stages of development is vital to the early detection of safety issues and avoidance of undue risk for patients. Any eClinical 2.0 solution should also communicate with existing pharmacovigilance programs to improve risk management.

Other important attributes of an eClinical 2.0 system include:

- The ability to manage the development process across multiple entities and multiple countries
- Integrated data capture that reduces data handling
- The flexibility to support adaptive studies through better data access and faster analysis of initial trial data
- The ability to incorporate and integrate imaging and diagnostic data as well as biomarkers, which are playing an increasingly important role in clinical trials
- Support for better information flow between sites and sponsor, and among sites, so all parties involved in a trial have access to the latest information; this is especially important as clinical trial programs become more global
- Tools that allow the sponsor to maintain consistency of data while working with a variety of vendors or outsourcing partners
- The capacity to incorporate legacy systems, as well as to accommodate corporate changes such as mergers and acquisitions

Overcoming the challenges

The greatest challenge to realizing the vision of eClinical 2.0 is the lack of industry-wide standards for the various aspects of clinical data. While CDISC has made significant strides in establishing data standards for protocol definition, eSource and clinical data, greater cooperation is needed between all of the stakeholders (ie, pharmaceutical companies, contract research organizations (CROs), investigators, application vendors, and regulatory agencies) to more quickly create and implement standards that support seamless data exchange beyond the core clinical data. Establishing these standards may be difficult, but they are absolutely essential if the benefits of eClinical 2.0 are to be achieved. Standardization of data will ultimately save time and money, and improve quality, at every phase of development.

While standardization is the greatest challenge, there are other obstacles to eClinical 2.0 that must be addressed, such as:

- Assimilation and integration of legacy data systems
- Overcoming the industry's traditionally slow adoption of new technologies, a position that is incompatible with today's competitive realities
- Choosing the right path; with multiple sources of data to be integrated and no single vendor with a comprehensive solution, the selection of eClinical 2.0 solutions will be challenging. The key to making the right decision will be selecting experienced partners who can demonstrate the ability to deliver the greatest benefits in the shortest period of time

Reaping the benefits of eClinical 2.0

Despite the many challenges to be overcome, the rewards of an integrated eClinical 2.0 system will make the effort worthwhile. The essential benefit will be the ability to make better clinical decisions faster, a top priority for every trial sponsor. With broader and faster access to integrated data from pre-clinical testing and early-phase trials, results about potential new compounds can be analyzed more quickly and thoroughly, allowing sponsors to make earlier (and better informed) decisions about whether to proceed with larger and costlier later-phase trials. As a result of this greater access to in-depth, integrated information from the beginning of the drug development process, pharmaceutical companies should be able to greatly reduce or eliminate one of the most costly and problematic issues facing the industry – the failure of a compound during later phase trials because of efficacy or safety concerns.

An equally important benefit is increased patient safety and improved risk analysis. With an integrated database of safety data beginning with early phase data, sponsors and investigators will be able to detect and understand product issues earlier in the development process, which will help keep trial participants safer and could greatly reduce the chances of unforeseen safety and efficacy concerns. Readily accessible safety data is also essential to support stronger pharmacovigilance programs that meet stricter regulatory requirements and provide essential information for better risk management.

A third major benefit will be the ability to design better and more cost-efficient clinical trials. As drug development costs continue to spiral upward, more efficient trial design is imperative.

With data modeling and adaptive trial systems supported by an integrated database of early-phase trial data, sponsors can design later-phase trials that provide the right information from the right patients at the least cost.

The ultimate industry benefit of eClinical 2.0 is the ability to use the integrated information to see the 'big picture' of a compound's characteristics as it progresses through clinical development, and make the right decisions about that compound's future. The result will be better, and safer, pharmaceutical products that reach the market more quickly, at a lower development cost, a benefit for everyone.

With the promise of such dramatic benefits, and the pressure facing the pharmaceutical industry today, the need for eClinical 2.0 is clear. The industry must undergo a paradigm shift to adapt to these new realities, and eClinical 2.0 is essential to the success of that shift. Equally important, this is not a 'blue sky' vision. The technology exists now to implement these changes. Trial sponsors could see major improvements in data interchangeability and single point-of-entry data collection within just a few years if the effort gets underway immediately.

Even though the challenges may seem daunting, the real risk lies in doing nothing and getting left behind as global market continues to evolve.

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