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In the next issue of
EDC Today:

The Importance of
Specifications

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System Migration

EDC Today is an independent publication on current information and issues in Electronic Clinical Systems (ECS) strategies and technologies for the Biotechnology and Pharmaceutical (Biopharma) industry. Each month we examine topics related to ECS theory, technology, practice, or implementation.

EDC Management understands that in the real world things change and where computer, networking, and communication technology is concerned, change is nearly a daily, relentless occurrence. Where once, computer-based applications remained relatively unchanged for a number of years, running on expensive hardware that was retained for as long as it functioned, now computer-based applications come and go quickly, and the hardware it runs on has become an inexpensive (and pervasive) commodity. To add to the burden of technological change are evolving regulatory requirements that have roots in our society's ongoing shift from paper-oriented work to the brave new world of electronic-forms and records.

In this issue, we explore the impact this fast paced change has had on Clinical Trial Management Systems (CTMSs) and/or Internet-based Electronic Data Capture (EDC) systems and discuss what needs to be done in order to migrate from the old faithful legacy CTMS to one that is currently up-to-date insofar as technology and regulatory requirements.

I. Introduction

There are many reasons why migration has become a very important topic amongst biopharma professionals over the past few years. One of the largest impetuses to change that has fueled system migrations has been evolution of computing from the mainframe/terminal to the inter-networked client/server environment.

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Software has evolved from character-based terminal applications, to Windows® graphical user interfaces (GUI), to elaborate Web-enabled applications. Software vendors that were unwilling or unable to keep up with the times lost market share; many have faded into obscurity, and some are no longer around to support their products. New vendors too, have come and gone, leaving some customers of their products stranded with applications which now require migration. The very pervasiveness of inter-networked servers and client computers caused a shift in the paradigms used to develop software used to capture and store clinical trial data. The widespread adoption of the Internet led to new software development tools (such as Java) and hence, Web-enabled applications.

The growing tide of computerization in offices worldwide has led to electronic records replacing paper files, and increasingly the regulatory bodies all over the world realized they had to develop guidelines and rules for how electronic records and electronic signatures would be maintained in a heavily regulated environment. The Food and Drug Administration (FDA) attempted to address electronic records in the early drafts of 21 CFR Part 11 and its associated guidelines and commentary.¹ Other regulatory bodies did the same. As the regulations gained shape, software had to be modified in order for it to be made compliant. Thus change in the industry led to a regulatory change, which in turn led to changes in software, leading to the increased awareness of the need for system migrations.

Finally, the evolution of standards such as those created by CDISC and similar initiatives has also led to changes being made to software to incorporate features deemed desirable, such as support for export and import of data in XML format.² Again, these changes to software have led to awareness of the need for system migrations; in this case, the new features found in the software may greatly help reduce the effort required to perform future system migrations.

The end result of all these changes has been the increasing move from legacy CTMS to next generation CTMSs, to expanded use of EDC, to expanded use of CDISC-based and similar standards, and regulatory recognition of the issues surrounding the electronic records. In short, more biopharmas are considering, or performing, more system migrations than ever.

II. What is Migration?

Data Migration, as defined by Webopedia, is:

The process of translating data from one format to another. Data migration is necessary when an organization decides to use a new computing system or database management system that is incompatible with the current system. Typically, data migration is performed by a set of customized programs or scripts that automatically transfer the data.³

Based on this definition, it is plain that migration from an old to new system is a special application of change control precepts and usually a one-way, one-time endeavor (e.g., you can't go back, short of restoring your system from backup media). Therefore, it should be obvious that a successful migration is the result of a well-managed change control project.

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III. It's a Lot of Effort, Isn't It?

Migrating to a new Clinical Trial Management System (CTMS) and/or Internet-based Electronic Data Capture (EDC) system from a legacy system requires a large amount of preparation and planning, carefully thought out checklists, and documented execution of ordered procedures.

The size of a migration project depends on how much data is to be migrated, how many systems will be migrated, and the ease of exporting and importing data, among other factors. A migration can be a very large project if there are many legacy systems being phased out and being replaced with a new system (and a still larger project if they are replaced with a number of new systems). Also affecting the magnitude of the project is the number of ongoing studies (as well as the size of such studies) and the amount of clinical data (both trial data and supporting data such as Codelists and dictionaries) being brought forward. The ease in which data can be exported from the old system and loaded into the new system will also be a factor in the size of the project. Sometimes overlooked in planning a migration project is the impact of reworking, abandoning, or replacing ancillary systems that have, over the lifetime of the legacy system, been developed and integrated with the old system.

IV. Where Does One Start?

If a migration has never been performed at your site, it may be a good idea to start with your change control procedures (SOPs) and use your procedure for upgrading a system (either a CTMS system or even “just” a computer workstation). These processes have the same “core operational philosophies” in that they will seek to:

- a) Minimize the risk of unexpected data loss via use of back up strategies.
- b) Minimize the risk of system loss by testing the upgrade on a “development” environment machine.
- c) Minimize disruption by anticipating the impacts of the change, such as impact of reworking, abandoning, or replacing ancillary systems (in this case, by inventorying the ancillary systems and their functionality and determining what will be done previous to, concurrently, or post migration with these systems).
- d) Minimize downtime by scheduling all activities at strategic times and by having working “roll-back” or fail-over plans.
- e) Minimize productivity losses (e.g., hold advance training sessions for users that will be expected to use the new system).

Also, any existing SOPs on clinical trial data archival will be useful. Key to the migration process is determining what clinical trial data will NOT be migrated to the new system (but rather archived and taken out of “active production”). Many people would migrate only that data absolutely needed. Other people disagree with this approach. In fact, some people suggest that every migration should take 3 steps: 1) data export from old system, 2) archival, and 3) import of data into new system. In any event, it is likely that at least some of the data found in the legacy system will require archiving.

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V. What and Who Will Be Involved?

A “software version update” where software and data are left in place and the update applied, usually as a “patch”, may not be considered a migration by many, and might be the least troublesome system change (that is, if your vendor thoroughly tests their updated software as well as their updating software) but the same care should be taken with updating critical clinical systems as with performing a migration. Avoiding the situation where either the data or the system being rendered corrupted or damaged is paramount.

For the purposes of this discussion, a “migration” is that where data is moved from an old system into a new system with the expectation of the new system replacing the old system in production. The system running the application may require one or more components be updated during the migration; that is, the server and/or client hardware, their operating systems (e.g., Windows XP), the middleware such as upgrading the version of the Relational Database Management System (RDMS, such as Oracle), supporting software such as the JAVA runtime environment, networking protocol(s), internet browser (the application, its configuration, or even version), and/or the actual application software itself.

Upgrades to server operating systems can entail considerable effort in and of themselves. The changes made by Microsoft between Windows NT and Windows 2000 (or Windows NT and Windows 2003) were immense and upgrading from NT to 2000 (or 2003) is a data migration project in its own right (i.e., user accounts, and other data was moved into a new database known as the Active Directory; security and other policies were largely revamped).⁴

Upgrading or changing an RDMS is also a project of considerable magnitude. In the case of updating an operating system and/or an RDMS, it may well be easiest to start with unused hardware and build a “test bed” to which other software is systematically added and tested for correct functioning before the next software layer is added. With the cost of hardware having fallen to new lows, this approach has much merit.

Loosely speaking, the escalating order of effort required for migration is as follows:

- Migration to new minor version (i.e., relatively new software to the latest software)
- Migration to new major version (i.e., old software to the latest software)
- Migration to new vendor (not to forget that user training will be needed)
- Migration of more than one legacy system to one or more new systems

Compounding the effort will be how active the application is, the more currently conducted studies, the more active the application and the more effort to schedule and perform work around current production requirements. Since many migration tasks will, by necessity, be performed by the biopharma Information Technology (IT) staff, it is important the clinical team be involved in working out project timing considerations (i.e., your IT department may not know your clinical schedule!).

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Finally, when migrating clinical trials data, consideration should be given to those components to be migrated – which and what part of dictionaries, Codelists, table definitions, item definitions, page layouts, form field and page level code, edit-checks, entry systems, user roles and accounts (access), and finally, the actual clinical trials data and its allied audit trail(s) should be migrated to the new system.

It should be noted that a number of consulting vendors offer migration services, many of them stressing the project management aspect of a migration. While a biopharma may not wish or need to hire a consultant, the project should definitely be run by someone that is detail-oriented, remains focused on the task at hand, has good project management skills, is empowered by upper management, and works well with people from a number of teams having vastly differing skills and talents. A migration may seem intimidating to many, especially the novice, but with care, adherence to change control and archival precepts, and enthusiasm, the job can be done.

VI. Conclusion

The increasing need to migrate is being driven by technological and regulatory change. The evolution of computing architecture and the widespread adoption of the Internet combined with the increasing reliance on the computerized office have led to generational change in clinical trials software and the regulations that apply to the use of this software. Where software remained relatively unchanged for several years in the 1990s, software now changes annually, quarterly, or even monthly (e.g., Microsoft's Windows Update). Not all software changes will require migration, but they do require planning and making use of change control precepts.

The widespread adoption of electronic records has led to regulations covering the use of electronic records as well as electronic signatures. As the regulations evolved, clinical trial applications were changed in order to allow regulatory compliance. Those vendors of legacy systems that could not or would not update their products have fallen by the wayside or offer entirely new applications, forcing some of their customers to migrate to new vendors or new applications.

The ongoing effort to establish clinical trial-based standards such as CDISC's ODM have finally reach a level of maturity and stability – they may, in fact, ease the effort required to export and import clinical trial data by providing a vendor-neutral, cross application, migration tool, as well as provide a format for archival.

All these changes has meant there is an increasing need to migrate the fruits of clinical trials from legacy systems to the latest generation of CTMS and EDC systems. While there are a lot of components involved in a migration, a well-managed change control project can result in a successful migration.

Resources

¹ http://www.fda.gov/ora/compliance_ref/part11/FRs/background/pt11pxf.htm

² <http://www.cdisc.org/standards/index.html>

³ http://www.webopedia.com/TERM/D/data_migration.html

⁴ <http://www.microsoft.com/windows2000/server/evaluation/features/dirlist.asp>



Who's behind the research?

Our lead researcher, Kirk Mousley, PhD received BS and MS degrees in Electrical Engineering from MIT and a PhD in Computer Science from Lehigh University. He has been the President of Mousley Consulting, Inc. since its founding in 1993 and has directed the company's efforts in the areas of clinical database design, data editing/cleaning, document management, and submissions.

Karl Mousley received his BS in Mechanical Engineering from Rose-Hulman Institute of Technology and a MS in Computer Science from Villanova University. He has been a senior member of the technical staff at Mousley Consulting, Inc. since 1993. Among his significant accomplishments are the investigation, evaluation, and implementation of new computer technologies for clinical data management systems and developing strategic plans for integrating these technologies into current systems. He has extensive experience preparing Standard Operating Procedures (SOPs).



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