CASE STUDY

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Extended Enterprise Learning

Hosted LMS Technology Allows Centocor to Deliver Mission-Critical e-Learning to Study Site Personnel in Clinical Trials

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IN THIS CASE STUDY

Hosted on-demand software can deliver the benefits of e-learning and learning management system (LMS) technology to a broad enterprise audience – one that extends beyond the traditional definitions of employee-centric corporate learning. Operational organizations (not just HR and corporate departments) can leverage hosted learning technology to achieve business goals and objectives in ways not seen even five years ago.

Centocor (a subsidiary of Johnson & Johnson and a leader in biomedicine) is applying technology and best practices to develop and deliver blended-learning programs that support human clinical trials, which are mission-critical operations for biotech and pharmaceutical companies. In order to ensure that studies are conducted according to good clinical practices, Food and Drug Administration (FDA) regulations and standard operational procedures (SOPs), companies roll out massive instructor-led training (ILT) programs for hundreds or sometimes even thousands of investigative site personnel, such as doctors, nurses, clinicians and study monitors.

By implementing an LMS and developing e-learning modules, the clinical trial management group at Centocor has boosted the productivity, cost-effectiveness and flexibility of its learning programs for study site personnel. This case study will examine how Centocor:

- Identified a key business process in need of automation – training on the electronic data capture[1] (EDC) system used by study site coordinators, investigators and data reviewers during clinical trials;
- Implemented a hosted, on-demand LMS to both minimize administrative overhead and to solve the "corporate firewall" issue for non-employee learners outside of Centocor;
- Took a blended approach to training study site personnel by combining self-paced e-learning, hands-on instructor-led training and virtual meetings;
- Managed the hosted LMS and e-learning content development process through an operational clinical trial management group that reports to research and development;
- Utilized the LMS for self-enrollment and registration, and to deliver e-learning content and assessments;
- Partnered with its LMS vendor and provided subject matter expertise to develop interactive e-learning content; and,
- Achieved a significant cost-savings model based on e-learning versus instructor-led training, as well as streamlining operations and administration.

1 An "electronic data capture" (EDC) system is a computerized system designed for the collection of clinical data in electronic format for use mainly in human clinical trials. The growing use of these systems is driven by the benefits derived in time savings, cost reductions and increased efficiency. Source: http://en.wikipedia.org/wiki/Electronic_data_capture.

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Company Overview

Centocor is harnessing the power of world-leading research and biomanufacturing to deliver innovative biomedicines that transform patients' lives. Centocor has already brought innovation to the treatment of Crohn's disease, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, ulcerative colitis, pediatric Crohn's disease and psoriasis.

The world leader in monoclonal antibody production and technology, Centocor has brought critical biologic therapies to patients suffering from debilitating immune disorders. Centocor, Inc. is a wholly owned subsidiary of Johnson & Johnson, a worldwide manufacturer of healthcare products.[2]

Figure 1: Centocor at a Glance

- Founded in 1979
- 2006 sales and revenues of $385 million
- 3,000 employees
- Subsidiary of Johnson & Johnson since 1999

Source: *Centocor, 2007.*

Business Environment

Clinical trials are essential business operations for pharmaceutical and biotech companies. These scientific research studies are designed to find better ways to treat or prevent diseases, often by comparing a medication or medical device with a placebo or standard medical treatment. Human trials help prove the safety and effectiveness of new treatments, and discover new uses for existing drugs. Although trials vary greatly in size, they can involve up to hundreds of study sites, and thousands of clinical personnel and patients.

2 Source: Centocor, "About," http://www.centocor.com/centocor/index.html#.

As the volume of information collected in clinical trials continues to grow, data collection and management is becoming a priority for the life-science industry. Capturing data in a more accurate and timely fashion is a critical component to reducing time to market for potential new drugs.

Additionally, reliable clinical data is the lifeblood of research. For a clinical trial to reach a successful conclusion, every aspect of patient data capture and recording must meet stringent quality and control standards.

In 2001, Centocor adopted a commercially available electronic data capture (EDC) system from a market-leading software provider. Going from a paper-based data entry system to an electronic system triggered a reexamination of the manual, instructor-led EDC training program for study site personnel.

Centocor's senior-level management team studied the situation and determined that a new approach to learning was needed. They believed that the computer-based EDC system, and other study-related procedures and protocols, could be taught more effectively using self-paced computer-based and web-based training (e.g., e-learning). The challenge was how to leverage the technology to train non-employees, such as study site investigators, who are restricted from accessing internal corporate computer systems.

KEY POINT

Electronic data capture (EDC) systems enable accurate, real-time creation, modification, maintenance, archiving, retrieval and transmission of clinical data.

Learning Environment

Decentralized Management Model

As is typical at most life-science companies, clinical trial training is a separate entity from other corporate learning programs, with its own funding sources, oversight and governance. At Centocor, a clinical trial management (CTM) group is responsible for the training and compliance of study site personnel. This clinical operations group manages late-stage trials (phases I, II and III), and reports to the research and development organization.

Many other corporate learning initiatives and programs exist at Centocor, such as new employee onboarding, quality training, role-based training, career development and compliance – but these are decentralized among the business units and departments. For example, each department manages and delivers its own employee orientation program, usually consisting of one day of general information, and a second day of role and department-specific learning. In general, learning and development (L&D) activities are initially managed, tracked and supported by the HR department, and then later moved down to the departmental level.

KEY POINT

While other corporate learning programs exist at Centocor, these are decentralized among the business units and departments.

Extended Enterprise Audience

Centocor typically has as many as 20 to 25 clinical trials actively in progress. Each study can span as many as 300 investigative sites, such as doctors' offices and hospitals, and can involve up to 1,000 people.

While the potential total audience for clinical trial training may be more than 10,000 individual learners at any given time, demand for clinical trial training ebbs and flows as new drug studies start and existing ones end. On average, the clinical trial management group actively trains fewer than 2,000 people at once.

These learners can be grouped into the following three principal constituencies.

- **Study Site Personnel** – People who work at the investigative site, including study coordinators, study site investigators (e.g., clinicians, nurses, physicians, monitors) and data reviewers. These people are not employees of Centocor.
- **Centocor Employees** – A study team of approximately 10 people is assigned to manage each clinical trial. The study team is responsible for all aspects of the initiation, maintenance and completion of clinical trials / programs, including delivery of training to study site personnel.
- **Contract Research Organizations (CROs)** – These partner companies provide clinical trial management services.

Goals of Training Study Site Personnel

The main objective of clinical trial training is to give study site personnel the knowledge and skills needed to perform their respective roles and functions during the investigation.

In terms of EDC system training, specifically, learning requirements are clearly spelled out in an FDA document, entitled *Guidance for Industry, Computerized Systems Used in Clinical Investigations*[3].

> *Those [companies] who use computerized systems must determine that individuals (e.g., employees, contractors) who develop, maintain or use computerized systems have the education, training and experience necessary to perform their assigned tasks (21 CFR 11.10(i)).*
>
> *Training should be provided to individuals in the specific operations with regard to computerized systems that they are to perform.*
>
> *Training should be conducted by qualified individuals on a continuing basis, as needed, to ensure familiarity with the computerized system and with any changes to the system during the course of the study.*
>
> *We recommend that computer education, training and experience be documented.*

To ensure compliance with this FDA recommended guidance, Centocor restricts access to the EDC system to trained users only. Certification to a specific level of training is required to obtain a user account on the system.

Other compliance-type issues that are addressed on some level with clinical trial management training include:

- Study protocols;
- Standard operational procedures;

KEY POINT

FDA guidelines (as well as those of other organizations) mandate strict compliance with regard to the use of any systems and the training of those systems.

[3] Source: U.S. Food and Drug Administration, Center for Drug Evaluation and Research, "Guidance," http://www.fda.gov/cder/guidance/7359fnl.htm.

- IRB / IEC[4] requirements;
- FDA regulations, if applicable;
- EU clinical directive, if applicable;
- ICH[5] Good Clinical Practice guidelines, if applicable; and,
- Local regulatory requirements.

Training Challenges

Training study site personnel have some challenging and unique requirements. Role-based learning models are needed to handle the multiple job functions and job profiles, such as online and offline EDC users. Assessments are necessary to document measurable learning comprehension and uptake. A system is required to record course completions, assessment scores and certifications.

Most importantly, there is a need for continuous EDC system learning. Certified users must be retrained for every new system upgrade. Additionally, clinical personnel turnover at study sites can be very high – as much as 100 percent every few months.

Compounding high site personnel and CRO turnover is an issue somewhat unique to clinical trials, called "database lock." Several times during a study, all data entry will come to a halt and the database is locked, so data quality can be checked by statisticians. The data cleaning and query resolution process lasts approximately one week. After the trial resumes, the CTM team often finds that there are several dozen new study site personnel who need EDC system training from Centocor.

KEY POINT

The very nature of clinical trials present an environment in which many different types of training challenges exist.

4 An "institutional review board / independent ethics committee" (IRB / IEC, also known as ethical review board) is a group that has been formally designated to approve, monitor and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the subjects. Source: http://en.wikipedia.org/wiki/Institutional_Review_Board.

5 International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

Early Approach to Training

Prior to the acquisition of an EDC system in late 2001, Centocor was using a paper-based data entry system. Training of site personnel was administered manually and delivered by study team members (who acted as instructors). A "train-the-trainers" model was used to develop the learning program for each clinical trial. Subject matter experts (SMEs) from research and development trained the study team, who then trained study site personnel.

There were numerous issues associated with this approach, including the following.

- **High Expenses** – Travel to global study sites and related expenses made the learning programs very costly to deliver. Centocor was spending approximately $1 million on training study site personnel for each clinical trial.
- **Inflexible Delivery** – The need to schedule face-to-face training time made it too difficult and time-consuming to deliver continuous training to address the issue of employee turnover at study sites and during database locking.
- **Error-Prone** – The paper-based record keeping system for training was unreliable, and made the certification and reporting process cumbersome.
- **No Automation** – Too much time was spent on learning administration tasks, such as student enrollment and registration.

Learning Management System

In late 2002, Centocor approved an initiative for the clinical trial management team to acquire and implement e-learning and learning management system (LMS) technology for study site training. The projected cost-savings in streamlining paperwork, travel and other overhead costs provided a solid business case for implementation of a new software system.

★ BEST PRACTICE

Organizations need to develop a solid business case to obtain senior management buy-in and support.

The overriding requirement in the team's search for a solution was the need to accommodate study site personnel and contractors employed outside the company. Centocor's information systems lie behind a network security firewall that protects it from outside attack by hackers, or viruses and worms. Only credentialed Johnson & Johnson / Centocor employees or contractors with global IDs can access information systems behind the firewall from an outside client connected to the Internet.

The CTM team needed a hosted, on-demand learning management system that would allow access by both internal and external users. After a thorough review of the available options in the market, the team selected the u360 LMS from RWD Technologies. The software is hosted at RWD's data center, which is protected by its own firewall. This ensures the security of Centocor's trial data, yet allows outside users (such as clinical workers) to have authorized access to the system.

After developing a portal page (see Figure 2) and conducting a brief pilot program, Centocor rolled out the system to end-users in mid-2003. The initial 500 enterprise-user licenses have been increased to 1,500 licenses today.

The LMS allows Centocor to deliver e-learning courses and assessments to study site personnel, and then track lesson and course completions. The on-demand software and enterprise license model allows Centocor to roll out refresher courses quickly and easily, or stagger training to different geographic regions around the world. As a clinical trial starts up, Centocor will offer training to North American study sites first, knowing that these will usually complete the training quickly. Study sites in Eastern Europe (which typically take longer to complete training) will get access to the LMS later.

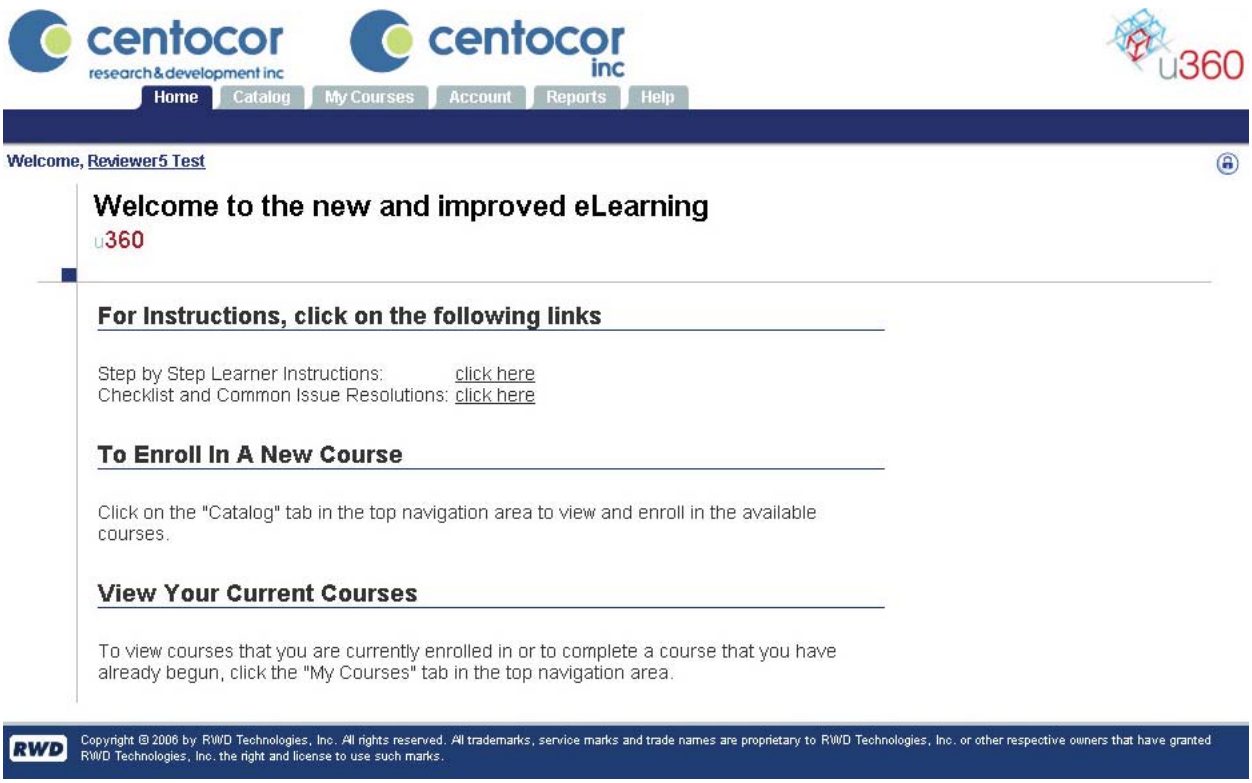
Although e-learning is currently delivered in English only, the CTM team is exploring the possibility of translating content into other languages (such as Spanish) to enable users to work in their language of choice. As Centocor expands its participation in global trials, LMS

ANALYSIS

According to Bersin & Associates research, organizations are consolidating LMSs across departments and business units. Exceptions may exist when the corporate data cannot (or should not) be accessed by external audiences or the LMS capabilities do not support external training.[6]

6 For more information, *The Corporate Learning Factbook® 2007: Statistics, Benchmarks and Analysis of the U.S. Corporate Training Market*, Bersin & Associates / Karen O'Leonard, February 2007. Available to research members at www.elearningresearch.com or for purchase at www.bersin.com/factbook.

Figure 2: Centocor e-Learning Portal Page



Source: *Centocor, 2006.*

support for concurrent usage in 25 languages provides capabilities for multinational trials.

In 2007, Centocor purchased a major upgrade to the latest version of the LMS software. Because Centocor had not purchased a major upgrade for several years, the company is using three new capabilities for the first time:

- Student self-registration;
- Student self-enrollment; and,
- Grouping users for reporting purposes.

Usage of these functions has fulfilled the company's goal of saving time on administration, and simplifying the process of getting users trained and certified in EDC courses.

ANALYSIS

Ease of implementation and usage are key advantages of hosted solutions (also called "Software as a Service" or SaaS), that allow operational groups to utilize LMS technology as competently as a corporate learning department.

Content Development

Since 2003, Centocor has developed nearly 20 e-learning modules on a wide range of clinical trial topics, including:

- Introduction to EDC for offline users;
- Introduction to EDC for online users;
- EDC version 3.3 for all roles;
- EDC version 3.9.7 for all roles;
- Adverse event and serious adverse event reporting;
- Informed consent process;
- Investigational product preparation;
- Investigator responsibilities;
- Evaluation of nail psoriasis; and,
- Supplemental training for independent joint assessors.

Centocor partners with its LMS vendor to build e-learning courses. In this shared development model, Centocor acts as the SME by providing information regarding course goals and objectives, written content in the form of PowerPoint presentations, assessment questions, and so on. RWD storyboards the e-learning module, records video and audio, animates graphics, and then codes the HTML pages. Beta courses are sent to Centocor for quality assurance review and testing.

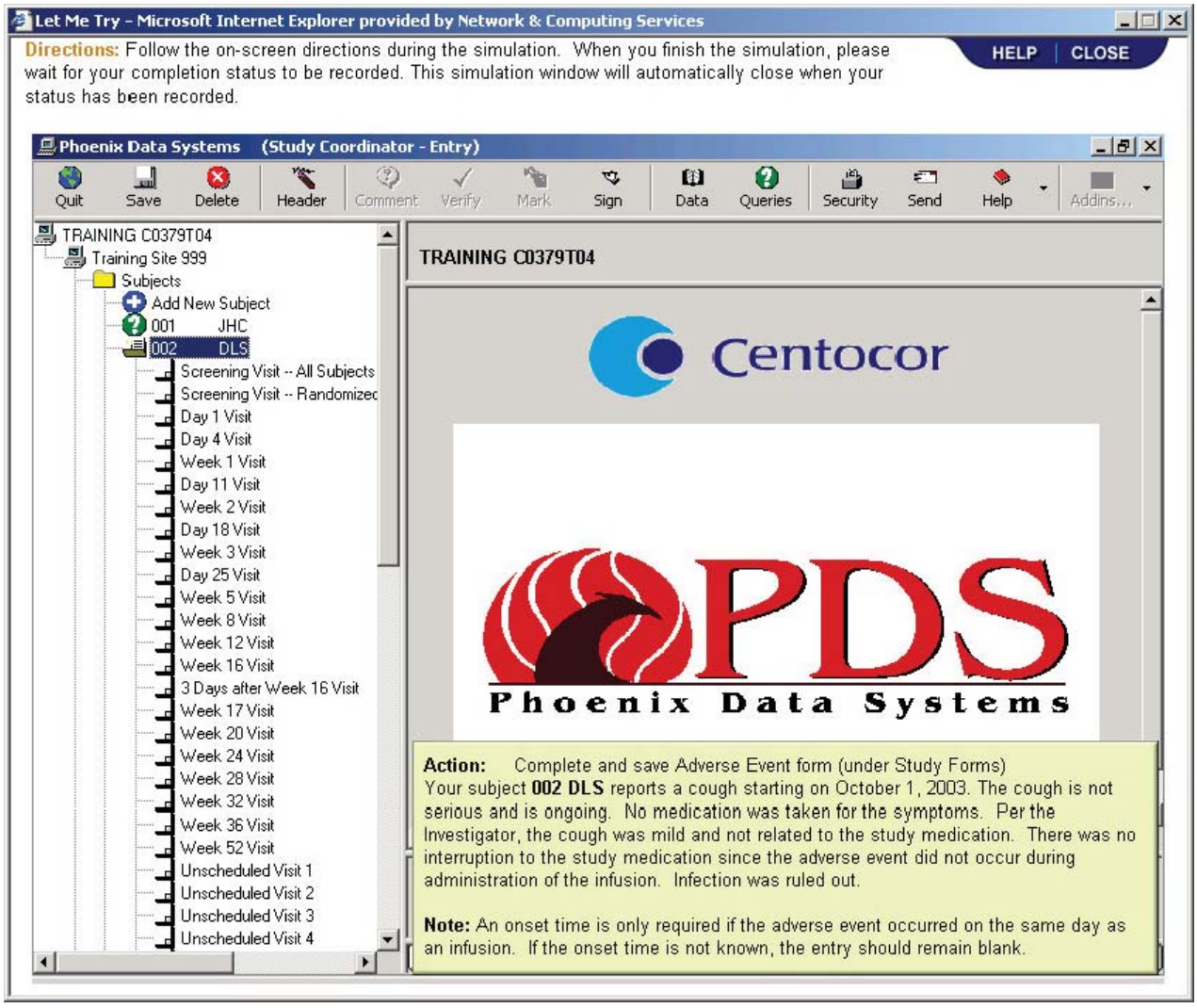
According to CTM managers interviewed for this case study, the ability of the solution to support various levels of interaction has contributed to its success. For example, individual lessons include many "Show Me" and "Let Me Try" simulations that allow the learner to click to learn more about a particular subject (perhaps with a video or animation), or practice a new skill or technique (see Figure 3).

Total e-learning development costs vary depending on the type of module. Simple PowerPoint presentations range in cost from $20,000 to $40,000, depending on the number of slides. More complex and interactive modules with many Show Me and Let Me Try simulations

★ BEST PRACTICE

Centocor partners with its LMS vendor to build e-learning courses in a shared development model in which the company acts as the subject mater expert and the vendor creates the actual courses.

Figure 3: Example of "Let Me Try" Simulation



Source: *Centocor, 2007.*

can cost from $40,000 to $80,000. e-Learning courses are less expensive to develop if they are based on content from an existing set of modules.

Today's Blended Approach

Centocor's current approach to training study site personnel is to blend different learning modalities – namely, self-paced e-learning

and instructor-led training. e-Learning is utilized to give students information about processes, procedures and how to use the EDC system. Learners complete a set of general and role-specific courses, and must pass knowledge assessments at the end of each lesson. Overall, two hours of e-learning has replaced what formerly took four hours of instructor-led training at a study site investigators meeting.

Today, instructor-led training is used for a very narrowly defined purpose. Case report forms are the paper or electronic forms that are used to collect data in clinical trials. Because the case report forms are unique to each study site, Centocor study team members still deliver this training in person.

As a third leg of the blended approach, the CTM team provides study site personnel with performance support tools, such as quick learning cards and printed manuals.

KEY POINT

Two hours of e-learning has replaced what formerly took four hours of instructor-led training at a study site investigators meeting.

EDC System Certification

The LMS is used to manage a formal certification process for EDC system training. The system tracks course completions and sends a completion email to the system administrator for each one. Upon completion of all required courses (which are based on the learner's role), the system administrator identifies the study team for the learner and prints a completion package consisting of:

- Cover letter;
- Two certificates;
- Completion email; and,
- Scoring report.

A study team member receives the completion package and reviews the scores to see if any additional training may be needed. The team member barcodes and submits the completion email and one certificate to the research and development archive for filing; the other certificate is sent to the learner.

Quarterly account status reviews occur to ensure that all users have completed all necessary training. The status of any user with incomplete EDC system training will become inactive.

Looking Ahead

Centocor's clinical trial management team is working on several new learning initiatives. The program getting the majority of attention and resources (at the time of this report) is a move to expand the blended approach to include virtual meetings.

In this scenario (which Centocor calls a "virtual investigator meeting"), e-learning courses are delivered via the LMS to prep students a few days or weeks before the virtual meeting. Next, the study team goes to a central location at which a combination of virtual meeting technology and teleconferencing is used to deliver the remainder of the training and information to all global study sites in one to two days.

This will virtually eliminate the need for travel and face-to-face training by the study team, resulting in an enormous gain in productivity and a reduction in expenses for Centocor.

Johnson & Johnson has an extensive Microsoft Live Meeting™ infrastructure in place, but the CTM team is unable to utilize it. As before, the problem is that external study site personnel and contractors cannot get past the network firewall. As this case study was being published, the CTM team was seeking out solutions for conducting these virtual investigator meetings from a hosted site using on-demand software technology.

★ BEST PRACTICE

Adding the technology to conduct "virtual meetings" will eliminate the need for travel and face-to-face training by the study team, resulting in an enormous gain in productivity and a reduction in expenses for Centocor.

Lessons Learned

Centocor has learned several important lessons that can be used by other operational organizations seeking to leverage e-learning and hosted learning management system technology.

Handling the Limitations of Licensing

The clinical trial management team is always evaluating the affordability of licensing costs. As mentioned earlier, the team carefully manages user

licenses to maximize the number of potential learners who can be covered by each license. By using staggered global training and other techniques, this operational group handles a learning audience the size of a large *FORTUNE* 500 company on the budget of a midsized business.

Thinking about Reuse When Building Content

When the CTM team members developed the content for the original EDC e-learning modules, they focused on making the content very specific to their particular system and version. Hence, there are two separate EDC e-learning courses – version 3.3 and version 3.9.7.

Today, the team is thinking of ways in which to build e-learning content that is less vendor and version-dependent. The goal is to be able to reuse content instead of rebuilding all of the content whenever the company adopts a new EDC system. One way to accomplish this goal is to separate higher-level concepts about EDC systems from details on ways in which to use a specific system.

ANALYSIS

By turning content into learning objects, Centocor is moving toward a new stage of maturity in content development management.

Conclusion

At Centocor, an operational group (not a corporate learning department) administers a learning management system and develops e-learning content for an extended enterprise audience. The advent of hosted, on-demand application software is a key enabling factor in the success realized by this clinical trial group, as well as hundreds of other operational departments across corporate America. With minimal resources and implementation expense, this category of LMS solution allows small groups to efficiently and effectively reach large audiences of learners.

Today, Centocor is using e-learning to teach study site personnel everything from how to enter clinical data to how to score joint inflammation. This not only ensures that study site personnel are performing at a consistent level, it also speeds data availability (e.g., the

KEY POINT

With minimal resources and implementation expense, this hosted LMS solution allows small groups to efficiently and effectively reach large audiences of learners.

point at which clinical data is posted to the database and available for reporting). Faster reporting means a quicker time to market for new drug treatments, which aligns with corporate goals of increased revenue and market share.

Appendix I: Table of Figures

About Us

Bersin & Associates is the only research and advisory consulting firm focused solely on *WhatWorks*® research in enterprise learning and talent management. With more than 25 years of experience in enterprise learning, technology and HR business processes, Bersin & Associates provides actionable, research-based services to help learning and HR managers and executives improve operational effectiveness and business impact.

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