Case Study

Electronic Data Capture Training for CRAs & Principal Investigators

INC Research, LLC. (Healthcare)
About the Customer

INC Research is a therapeutically-focused, contract research organization. It has a high performance reputation for conducting global clinical development programs of the highest integrity. The company provides a complete range of customized programs in therapeutic areas of specialty and in innovative pediatric and women’s health trials.

INC Research Trusted Process® methodology and therapeutic foresight leads their customers to more confident, better-informed drug, and device development decisions.

Customer Needs & Challenges

INC Research uses an industry-leading Electronic Data Capture (EDC) system for capturing, managing and reporting clinical research data, designed to help life science companies optimize their research investments by efficiently streamlining the clinical trial process. For successful clinical trial outcomes, it is important that a Clinical Research Associate (CRA) II/III/Senior completes project activities associated with monitoring functions for Phase I-IV clinical research studies. Additionally, CRAs continue to develop a solid understanding of the drug development process, Good Clinical Practices (GCP), and relevant regulations.

Systems training are very important for CRAs to perform source data verification according to contractual requirements. Efficiency in using EDC systems assures timely completion and submission of case report forms according to the Clinical Monitoring Plan and/or the Data Management Plan. It also ensures the timely and accurate completion of data clarification forms.

To achieve a more efficient process, the client wanted to deliver EDC (Medidata Rave) training courses to:

- Clinical Research Associates (CRAs)
- Principal Investigators
- Study Coordinators (SCs)

Our Approach

InfoPro Learning proposed that the training would not only offer conceptual knowledge, but also include achieving high-level skills. Additionally, InfoPro proposed that the content would be crisp, interactive, and impart experiential knowledge required to achieve the learning goals. The sound instructional design ensured that the training would deliver the content in easy-to-understand capsules. The training comprised of three modules:

- Knowing the features and benefits of EDC (Conceptual)
- Know the roles and related tasks within the EDC (Blend of Conceptual and Application)
- Using the EDC (Application and Simulation-based)
The InfoPro Learning Solution:

InfoPro developed high-quality, user-friendly, interactive, and self-paced eLearning courses. The training course incorporated illustrations designed to provide a rich learning experience. Relevant engaging animations were provided to the learner. A professional voice-over further added value to the learning experience. The overall learning solution consisted of:

- Concept-based training on the features and benefits of EDC
- Application-based training on the use of EDC
- Role-based workflow training for decision-making practices

Instructional Strategy

InfoPro understands the need for an appropriate instructional design approach that ensures learner performance leading to improved business results. The learning experience must be designed to manage and support the learner’s cognitive processes, such as cognitive load, rehearsal/encoding, and retrieval/transfer. Such a learning experience is designed using a wholesome conceptual framework provided by Dr. M. David Merrill’s First Principles of Instruction.

The framework indicates that any effective learning product or environment engages the learner during distinct phases. The phases may be listed as follows:

- Activation of prior experience
- Demonstration of skills
- Application of skills
- Integration of skills into real-life problems

In addition, the scientifically proven principles of instruction as defined by leading researchers Ruth C. Clark and Richard E. Mayer are applied as additional guidelines toward the detailed learning media design:

- Multimedia/Contiguity – Integrating words and relevant graphics
- Modality – Present content as audio narration rather than on-screen text
- Redundancy – Avoid presenting content as both, on-screen text and audio narration
- Coherence – Use concise words and avoid unnecessary graphics and sounds
- Personalization – Use simple words and on-screen coach characters

Design Strategy

InfoPro used two learning design models. One of them is our Business Centered Learning Design (BCLD) model. This model is used as an outer wrapper for developing solutions that have an impact on the perceived business value for the training course. The second model, Pebble-in-the-Pond, is used as an effective design model. This model is nested within the outer wrapper to utilize the power of the design framework. The Pebble-in-the-Pond model is utilized during the phases of Task Analysis and Design.

The course design is based on the existing eLearning standards used for the development of earlier INC Research training courses. The training course also includes rich and aesthetically pleasing media, high-quality demos and simulations, engaging interactions, and a variety of innovative presentation methods.
Learning Outcomes

InfoPro training courses provided development-oriented and individualized learning experiences that provided experiential, life-centered, and contextual learning, relevant for the learners. Additional learning benefits included the following:

- The client experienced an increase in impressive operational results in global, large-scale clinical trials
- Data managers can now achieve further success through the creation of a global clinical trial process that is standardized
- Improved handling of mid-study changes with minimum effort to address protocol amendments, specification changes and new requirements
- Trainees including CRAs, Investigators and SCs now leverage the benefit of using EDC (Medidata Rave) to enhance their performance.
InfoPro Learning – The Right Choice

InfoPro Learning helps organizations rapidly transform talent by focusing on Learning for Performance. A global, award-winning learning and training solutions company for nearly 20 years, InfoPro provides performance improvement strategies, blended learning solutions and managed training programs. At InfoPro, performance innovation, cutting-edge technology and a talented team are combined to deliver successful workforce solutions and business outcomes. InfoPro Learning is obsessed with helping customers build training capacity, advance their practices and respond effectively to changing learner needs.

For more information about InfoPro Learning, Inc., visit www.infoprolearning.com, call (609) 606-9984 or email us at info@infoprolearning.com