

Case Study: Clinical Data Sciences Organization

ePath Learning's LMS Technology and Support Services Helps Expedite Rater Training for Clinical Trials



Overview

Successful clinical trials rely on qualified raters to enlist suitable participants for the studies and to administer and score assessments correctly. Unfortunately, a rater's clinical experience alone is not enough to ensure proper data collection and accurate scoring of clinician-rated scales from trial to trial. You need a program tailored to the needs of your study, including rater qualification, training, and testing for those who will be vetting study participants.

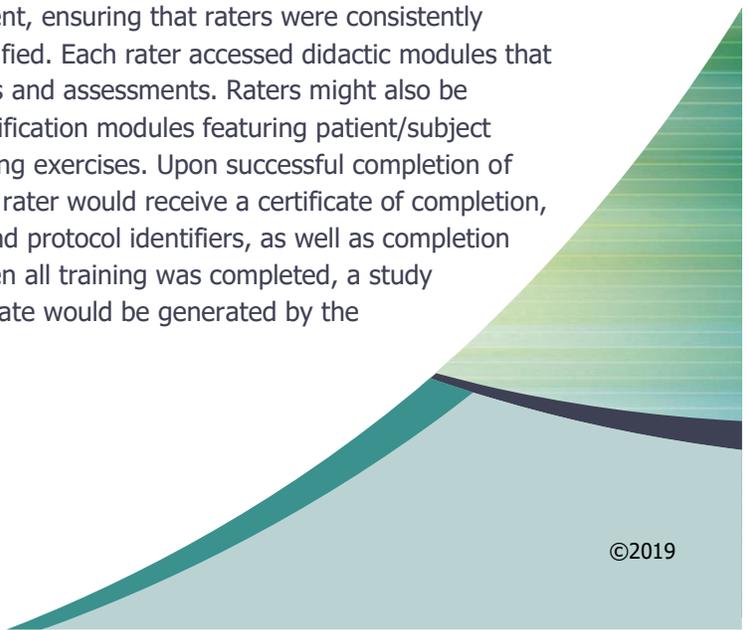
Our client is a clinical data sciences organization that delivers flexible and customized rater training for clinical trials.

To ensure that raters administer and score participant assessments accurately, there is a great need for rater training and qualification at the beginning of the study. Our client's approach is to assess each rater's professional experience and clinical knowledge, and then train potential raters on the specific rater scales and study criteria from the outset of the study. Only after clearly demonstrating proficiency in administering these scales and conducting patient interviews will a rater get assigned to a study. Our client trains thousands of raters for trials conducted around the world for a multitude of sponsors and protocols in support of a variety of therapeutic areas.

The Business Case for Implementing Validated LMS Technology

Prior to implementing ePath Learning’s LMS technology, our client was using excel spreadsheets and a homegrown system to manage their rater training. The system was difficult for both administrators and project managers to use, and as such, was not used consistently across all clinical studies. With only one person supporting the homegrown system, implementing and managing rater training was a cumbersome process that lacked key elements such as 21 CFR Part 11 compliance, workflow standardization, content flexibility, tracking, and up-to-the-minute insight/reporting on training analytics. Furthermore, the majority of our client’s sponsors were requesting that their rater training be accessible via a private and secure electronic portal. Given the client’s unique requirements, ePath Learning was their learning management technology partner of choice.

Unique Training Requirements	LMS Technology and Support Solutions
Custom Branding	Our client was searching for an LMS that would allow for custom branded portals for each sponsor and clinical trial. Each portal would be a centralized repository of study-specific documents. ePath’s support team created custom portals for each clinical study. Login pages were branded with client and sponsor logos and a consistent background theme was applied to each learning portal.
Prequalification, Testing & Surveys	Our client required that Raters upload their CV and take/submit a rater qualification questionnaire to verify them for the appropriate online training curriculum. When raters accessed the system, they were initially provided with a link to a survey, and CV upload that identified the rater’s experience. Based on the results of the survey and client criteria, the rater was assigned the appropriate learning path with a customized welcome message that provided them with a clear explanation of their training requirements. Upon completion of their requirements, the rater’s project manager would receive a completion notification.
Deliver Role-Specific Training Content and Certificates of Completion	Our client was looking to deliver just-in-time, role-based training, with rapid deployment of content, ensuring that raters were consistently trained, qualified and certified. Each rater accessed didactic modules that included interactive videos and assessments. Raters might also be assigned training and certification modules featuring patient/subject videos and interactive rating exercises. Upon successful completion of each didactic module, the rater would receive a certificate of completion, which included sponsor and protocol identifiers, as well as completion and expiration dates. When all training was completed, a study memo/certification certificate would be generated by the project managers.



Integrity of Data – 21 CFR Part 11 Compliance

A copy of all certificates remaining in the system and could be reported upon or batch-generated for study sponsors in the event of an audit. ePath's team supported the set-up of modules, videos, PDFs and assessments enabling project managers to focus on other equally important study-specific deliverables.

Our client required full system compliance with the FDA's 21 CFR Part 11 requirements. ePath's LMS technology supports the software validation requirements defined by the FDA, including robust features such as electronic signatures, automated versioning, data security, and a fully documented SDLC. Furthermore, our validation package streamlines your software validation process so that you can expedite the implementation of your LMS.

Comprehensive Reporting Requirements

Our client required the ability to generate comprehensive and detailed, real-time tracking reports, so study teams could easily monitor and manage study sites' training progress. ePath Learning's support team developed custom reports, including one that collated and tabulated essay and short answer questions in an easily exportable format. Progress reports were run, in some cases, on a daily basis, and were automatically emailed to project managers and sponsors.

Managed and Professional Services

To better optimize the time of their project management team, our client opted to utilize ePath Learning's Managed Services and Professional Services teams. ePath's Managed Services team was responsible for handling several aspects of the client's portals. To expedite the processing and to maximize efficiencies for the client, an exclusive online ordering system was developed. Upon initiation of a new study, specific needs and timelines were discussed, and the ePath team would commence work immediately on the new portal. In as little as three days, the new portals would be configured, branded and turned over to the client for administration. Our team also worked with the client to develop a customized training program for all new project managers. The training showcased a rater's progression through the materials, and provided instruction for system administrators regarding training content, maintenance of learner records, and reporting. Our team also provided JIT training sessions when crafting new processes or workflows for a particular study.

Our Pro Services team was responsible for creating templated course designs, defining editorial conventions, and optimizing media content for all modules. Client and sponsor branded login pages and portal themes were designed to enhance the online experience for raters in training.

Since implementing our LMS technology, our client has established themselves as leaders in rater training, which has positioned them to be far more competitive in the marketplace. As such, their business has grown exponentially across a variety of therapeutic areas in support of both Fortune 500 and biopharmaceutical clients. ePath Learning is honored to support over 50 clinical trials, both domestic and global, for our client and their study sponsors.

To learn more about ePath Learning's LMS technology and services, contact us today: sales@epathlearning.com or call us at 860.444.8090.