# LMS: A MUST FOR STUDY COMPLIANCE AND EFFICIENCY

TRIAL INTERACTIVE

*"Many organizations begin with addressing compliance training needs as part their rollout strategy. Compliance training refers to the process of educating employees on the laws, regulations, and company policies that apply to their day-to-day job activities. Regulatory compliance training is important for an organization because they are likely to be audited by regulatory agencies if there are suitable grounds for doing so."*

*- Clarkston Consulting* [8]

**OVER 87% OF USERS**

*[for all LMS use cases] have web-based LMS solutions.* [1]

# EXECUTIVE SUMMARY

Selection of an LMS software is mainly based on functionality (53%), followed by price (32%), support (5%), company reputation (3%), and software popularity (3%). An LMS is not worth much if functionality isn't its foremost selling point. [1]

## HOWEVER, THERE ARE THREE OTHER POINTS TO CONSIDER ABOUT AN LMS:

1. LMS is more than just a tool
2. LMS should be part of your study execution
3. LMS is essential because compliance is crucial for a successful study

As a Life Sciences organization, you work in a globally regulated environment that requires employees to Investigative site staff and any vendors participating in a study protocol and applicable regulations. This training is necessary to minimize risk of findings during regulatory inspections, but also to improve quality and performance to more effectively meet business objectives.

According to the National Institutes of Health on the topic of designing Good Clinical Practice into social and behavioral studies, "Investigators and clinical trial staff who are competent in GCP principles will be better able to assure that the rights, safety, and well-being of human subjects are protected; that clinical trials are conducted in accordance

with approved plans and with rigor and integrity, and that data derived from clinical trials are reliable." [2]

So, how do you adequately train your study teams to comply with industry guidelines? Your study teams need a learning management system (LMS) that efficiently and effectively delivers, manages, and tracks study protocol and regulatory compliance training and ensures qualification of GxP-compliant study team members.

This is so standard and expected of clinical teams, in fact, that the National Drug Abuse Treatment Clinical Trials Network [3] has a public-facing LMS specifically for training and education on Good Clinical Practice. [3] While not entirely the same as a company LMS, the adoption of LMS by institutions concerned with patient-centric, compliant, and effective studies is validation that study teams are expected to implement learning into their operations.

A compliance LMS is something that gives sponsors and QA teams real oversight and control.  Choosing the right LMS for your organization is critical to support learning and training goals across all areas of the company. at the LMS as an overall strategy and not just a tool.

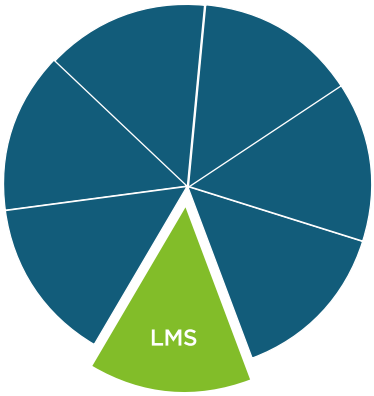
It's true that an LMS is still software, which is, in essence, a tool. It is also an exercise and set of organizational expectations that requires integration into the very business processes that support daily operations. The real value of a compliance LMS is to enable life sciences companies (i.e., pharmaceutical companies) to not only implement their learning process, but to define new and better learning processes and ensure that the result of training and learning is met. The result: performance improvement leading to a direct/indirect positive impact on speed and efficiency of operations, reduction of CAPAs and other distracting course corrections, overall reduction of risk of inspection/audit findings, and of course, cost savings and optimization of resources and investment capital. [4]


*"Departments that care about educating ... audiences are not investing in these programs because compliance rules require it but because these learning programs lead to a direct, measurable business impact..."*

*- John Leh, CEO and Lead Analyst at Talented Learning, LLC* [9]

# MAKING AN LMS PART OF YOUR STUDY EXECUTION:

## WHAT TO LOOK FOR IN A LEARNING MANAGEMENT SYSTEM?




- ✔ Compliant with FDA guidelines
- ✔ Title 21 CFR Part 11 [5]
- ✔ Role-based training that takes into account a number of factors unique to the specific role and organization. It puts the training in the context of the role and what it takes to perform in that role. [6]
- ✔ Audit trail that contains immutable record that keeps track of administrative actions performed in the system, such as important changes to course completion or enrollment status. The audit trail report provides written evidence of a sequence of activities that have affected specific operations, procedures, or events, and is useful to allocate the appropriate accountability in case of incidents, specifically pertaining to compliance. [5]
- ✔ Electronic signatures or "e-signatures" for employees to sign-off on their understanding of the information in a validated, Part 11-compliant environment. Leveraging this technology, you gain an auditable record of all activity associated with your critical information. [5]
- ✔ Reporting that provides sponsors or system owners easy access to data to analyze, and saves time by providing the option to create custom reports, extensive ad hoc query capabilities, and tracking of KPIs.
- ✔ Integration with a document management system (DMS) for version-controlled documents.
- ✔ Part of a fully integrated, end-to-end e-clinical product suite to align training directly with all essential clinical processes and compliance requirements.

## LMS IS ESSENTIAL TO YOUR STUDY TEAM'S SUCCESS

Life sciences companies live by compliance. Without the above considerations managed effectively in your organization, the risk of inefficiency, compliance failures, inspection/audit failures, and cost inflation abounds. Learning in business operations is no different than learning in academics: it is a foundation for predictable, positive outcomes.



**QUESTIONS?**
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# THE TRIAL INTERACTIVE GLOBAL LEARN ADVANTAGE

TransPerfect Life Sciences offers the Trial Interactive Learning Management System (TI Global Learn), providing organizations with a web-based, compliance-focused learning and training solution with flexible configurability and intuitive reporting for easy oversight. All of Trial Interactive's modules are 21 CFR Part 11 compliant.

TI Global Learn is built around adult learning theory [7] to provide "learning that sticks", with a wide range of customizable e-learning frameworks including integrated documents, videos, quizzes, fully SCORM-compliant modules, and certificates.

Role-based and competency-based learning ensures the learning experience is tailored to the role of the learner and training is aligned with their expected accountabilities. TI Global Learn also ensures that your employees and vendors are up to date with the latest compliance required by your organization and regulatory agencies.

Combining TransPerfect language support with a globally accessible platform means that international organizations can train across countries and languages and the LMS is accessible wherever required. TI Global Learn is mobile friendly and compatible with a wide range of tablets, smart phones, and other devices.

Connections to various APIs allow integration with document management systems, Oracle PeopleSoft, and other human resources IS systems. The single sign-on (SSO) feature ensures that users can automatically log in to TI Global Learn.

Integrations with various web conferencing platforms, such as Big Blue Button, Adobe Connect, and Google Hangouts enable face-to-face, live learning experiences. Administrators and students can connect to multiple cloud-based systems such as Google Drive, OneDrive, Dropbox, and more for adding content.

TI Global Learn is a part of our Trial Interactive e-clinical platform and can be used as a standalone service or as a fully integrated solution with Trial Interactive's eTMF, study start-up, and document management modules. The accessibility and agility of TI Global Learn facilitates a training experience that enhances overall efficiency in clinical operations.



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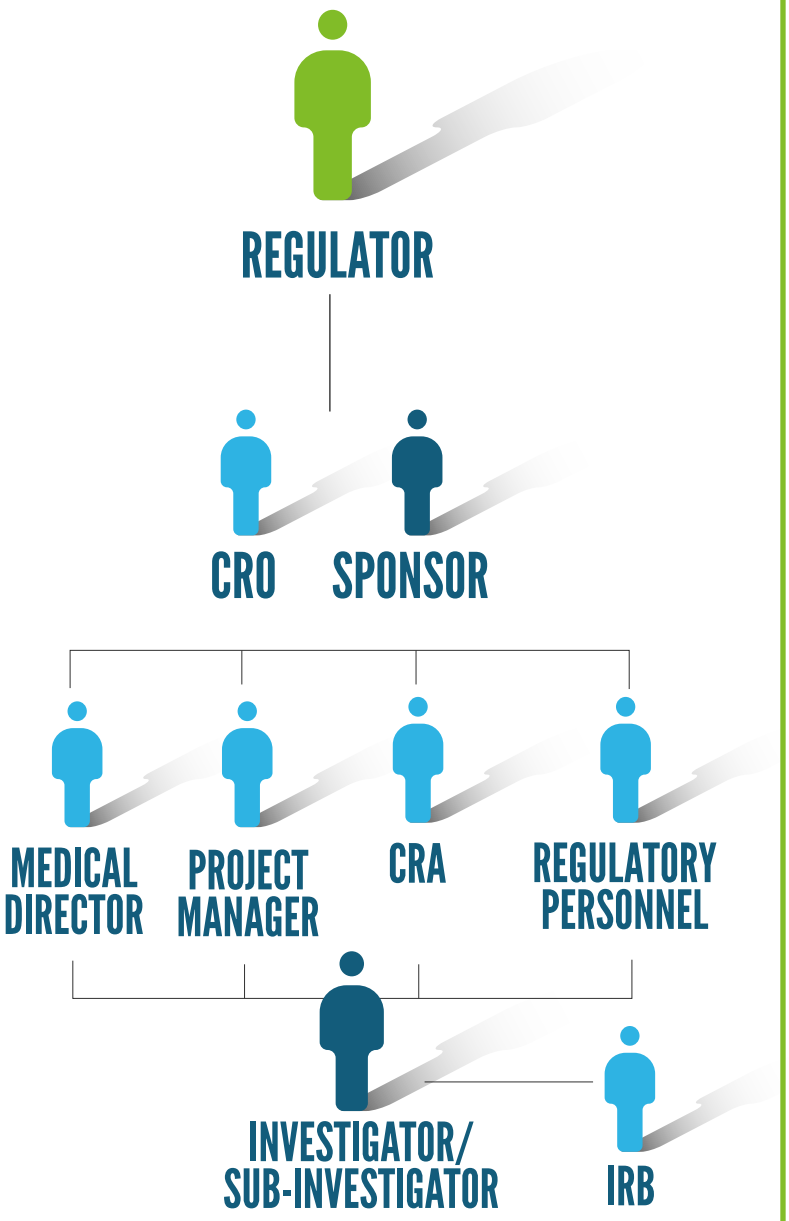
# TI GLOBAL LEARN PRODUCT DETAILS




## TI GLOBAL LEARN FOCUSES

on facilitating the required training for the performance of all roles supporting a study and ensuring complete and compliant training records that may be subject to review during a regulatory inspection. Ensure compliance with industry guidelines that include:

- ✔ Policy training
- ✔ Standard operating procedure (SOP) training
- ✔ Current Good Clinical Practice (GCP) training
- ✔ GCP training for monitoring clinical trials

## TI GLOBAL LEARN EFFECTIVELY ENABLES TRAINING FOR:

- ✔ CRAs
- ✔ Study Teams
- ✔ CROs and Vendor Partners
- ✔ Investigative Site Personnel



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# TRIAL INTERACTIVE FEATURES OVERVIEW

- ✔ Secure regulatory compliant training
  - Access SCORM-compliant training modules and activities
- ✔ Learn anywhere, anytime – including mobile
- ✔ Compliant with FDA 21 CFR Part 11 regulations
- ✔ Configurable learning frameworks (document, video, audio, etc.)
- ✔ Configurable branding and site design
- ✔ Robust and configurable user activity reporting
- ✔ Flexible platform allows for custom feature development
- ✔ Compatible with various plug-ins and external tools (LTIs)
- ✔ Active directory integration for easy user management with your existing infrastructure
- ✔ Localized for countries around the world in 75+ languages
- ✔ Ability to create e-learning courses in any language for a truly global experience

## REFERENCES


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