Reduce Clinical Trial Risk and Cost with Mobile Microlearning

Qstream's microlearning solution surfaces knowledge gaps of site monitors and clinical trial teams for remediation to reduce training cost and mitigate risk.

Qstream

Training Challenges Faced by Global Clinical Research Teams

Life sciences companies, pharmas, clinical trial sponsors and contract research organizations (CROs) strive to deliver the first breakthroughs in the development and release of new drugs and therapies to establish a unique offering or first-mover advantage. By bringing new or improved products to market ahead of other providers, pharmas are able to deliver much needed treatment to patients in need and build trust with healthcare professionals (HCPs) which will form a preference for their product and give valuable patient and professional feedback early in its lifecycle.

However, launching new pharma products is expensive, lengthy and bound by the strictest compliance mandates. By the time a trial reaches phase 3 or 4, inefficient recruitment and training of site monitors and clinical HCPs can quickly add to the cost, risk and length of the trial.

> **"Qstream is a common sense approach to a common problem that trainers and managers face every day."**
>
> — *Clinical Training Manager, Global Biopharmaceutical Customer*

The Challenges

Distributed Teams

The remote nature of site monitors and HCP teams puts demands on how to recruit, train, manage, and retain staff as well as oversee quality without blowing out costs.

Lack of Insight into Site Monitor Knowledge

Without the ability to assess gaps in knowledge and skills of site monitors, it is difficult to know what site monitors have retained and where they need help to create efficiencies by training only what is needed.

Adverse Events

Basic ethics dictate that patient safety is the main priority in any clinical trial. However, if an adverse event occurs, the reputations and legal damage can not only be severe, they can push out timelines and cost as trials have to be suspended, adjusted, repeated and reapproved under the strictest scrutiny.

Trial Complexity and Tight Timelines

There is added pressure for clinical trial managers to implement and control every step to ensure quality and accuracy of data, and adherence to good clinical practice (GCP) standards.

Changes in Standard Operating Procedures (SOPs)

Adherence to the latest GCP standards, trial protocol and SOPs push trainers to constantly update clinical site staff, data management center, and sponsors on the collection, processing, storage, and interpretation of clinical trial data.

Adoption of Risk Based Monitoring (RBM) Models

Working in an environment that can be constantly changing to adjust to an RBM methodology can mean retraining and heavy quality assurance oversight on site monitor activities.

> **"We needed to figure out where to start. What our site monitors know and what they don't know, so we could focus our efforts. Qstream's unique approach trims the fat so we can target individual competencies more effectively."**
>
> *— Clinical Training Manager, Global Biopharmaceutical Customer*

The Solution

Utilizing technology to execute on a culture of continuous learning that is engaging, mobile and measurable can help clinical trial managers and trainers reduce site monitor training budgets, improve their agility and help them avoid costly errors that throw trial timelines off track. How?

1. Engage site monitors and HCPs
2. Reinforce knowledge and skills
3. Identify knowledge gaps
4. Remediate
5. Adapt training plan
6. Repeat

Qstream Benefits

- Bring new drugs to market faster by changing behavior that will lessen time delays
- Improve patient health, safety, experience and mitigation of adverse events
- Reduce business risk and avoid future costs
- Decrease turnover rates of site monitors
- Keep site monitors compliant
- Decrease unnecessary site visit costs

Build Proficiency Through Engagement and Reinforcement

In later stages of clinical research and trials, site monitors are critical to the success or failure of the study. They must continuously learn, adapt, and adhere to new regulations and SOPs as well as maintain GCP standards. The global nature of large-scale phase 3 and 4 clinical trials makes it challenging and costly for clinical operations and training managers to reach this dispersed audience through traditional training methods.

Clinical leaders invest a significant amount of time and money on training to ensure that clinical trial data is accurate, timely and compliant. But training is not a one-and-done exercise. Clinical trials last for years, sometimes even decades, and many variables can and will change over that period.

For example, new SOPs, updated compliance requirements, and adapting or responding to new RBM indicators all effect how site monitors go about collecting accurate data. Therefore, there is a need to constantly keep site monitors trained through an engaging learning experience to keep knowledge and skills up to date.

Besides the need to be agile and updated, site monitors are only human and it can be easy to forget newly learned knowledge from a classroom, eLearning modules or other training methods if it is not reinforced. Knowledge quickly erodes over the course of a lengthy trial putting the clinical study at risk. Furthermore, it is incorrect to assume all site monitors learn using the same methods and retain the same information.

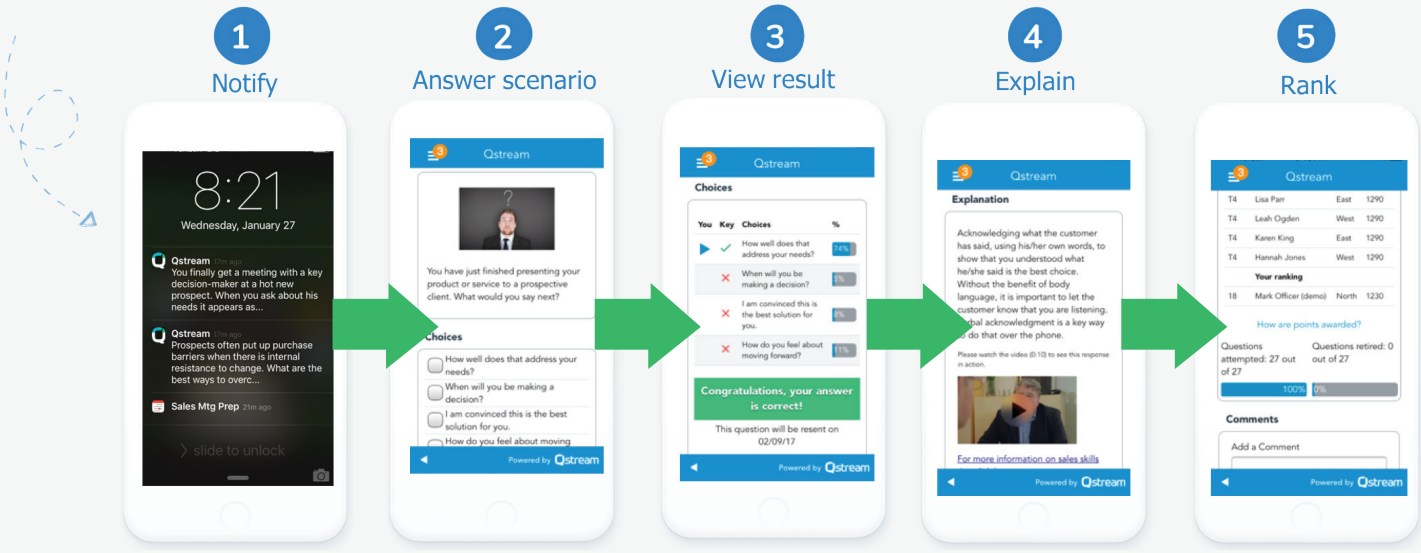
"The Forgetting Curve" shows that knowledge retention begins to drop immediately after training is conducted and that 79% of new information is gone within the first 30 days. Clinical trial leaders must be able to easily identify knowledge and skill gaps of their clinical trial teams during the course of a trial to avoid costly mistakes that might prevent new products being brought to market. Here are just some of the risks for not including knowledge reinforcement as a learning strategy:

- High turnover of site monitors
- New regulations requiring sponsors to update and monitor new risk measures
- Geographically dispersed site monitors which may cause variations in operating practices
- Lack of managerial insight into site monitors' level of skills and knowledge to remain within SOP alignment
- Clinical managers inability to identify knowledge gaps and provide coaching

Qstream's Mobile Microlearning Solution Enables Clinical Trial Teams to:

- Measure site monitor proficiency, competency, and performance
- Provide managers with analytics for personalized coaching opportunities with site monitors
- Change site monitor behavioral (soft) skills e.g., active listening, patient care, handling objections
- Identify knowledge gaps of clinical trial teams before adverse events occur
- Deliver scenario-based training without taking site monitors out of the field
- Improve site monitors knowledge retention of cognitive (hard) skills e.g., research objectives, side effects, data collection process
- Measure the effectiveness and ROI on large investments into training and RBM tools

Learning in the Flow of Work



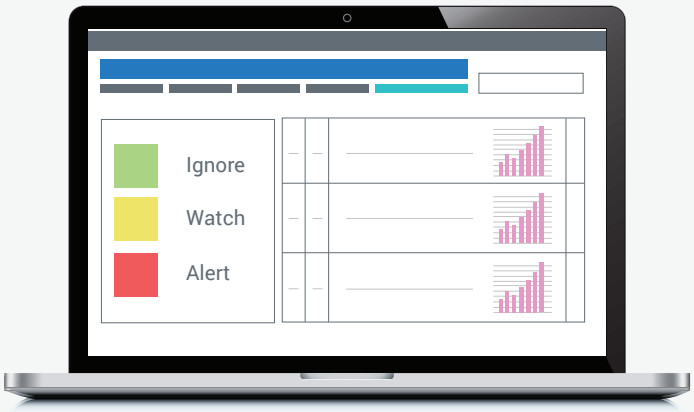
Possible Content Topics For Clinical Trial Training

- SOP training
- Protocol reinforcement
- ICH E6 (2) compliance training
- RBM methods and process effectiveness
- Sponsor management
- Field operations monitoring
- Compliance and regulatory affairs
- Monitor training
- Clinical research operations
- Clinical trial manager enablement

Example: Scenario-based question for remote site monitors

When you review your risk management site tool, the following items are yellow:

Overall Score | Resolution Score | Issue Score | Data Entry Score



Should you schedule an on-site visit to address the significant number of issues?

Choose correct answer:

- [ ] No, just because the site is in the yellow tier does not constitute a full day of work. Root cause analysis needs to be done
- [ ] No, you should only schedule an on-site if all the indicators are red
- [ ] Yes, an on-site visit should be scheduled so that a root cause analysis can be done
- [ ] No, an off-site visit should be scheduled to review the issues

Measure RBM Monitor Training Impact

Proficiency Heat Map Pinpoints Site Monitor Knowledge Gaps

Initial Proficiency

Topic	Americas	Europe	Average by Topic
Onsite Visits	55%	70%	63%
Offsite Visits	53%	56%	55%
Source Data	60%	55%	58%
Site Relationship	63%	59%	61%
RCA on KPIs	65%	62%	64%
Average by Geography	59%	60%	60%

Current Proficiency

Topic	Americas	Europe	Average by Topic
Onsite Visits	85%	75%	80%
Offsite Visits	71%	83%	77%
Source Data	71%	75%	73%
Site Relationship	79%	78%	79%
RCA on KPIs	82%	88%	85%
Average by Geography	78%	80%	79%

- Reveal gaps correlated to performance for precision coaching opportunities
- Identify knowledge gaps in specific topics and by geographies/sites
- Drive high engagement rates due to simple and fun learning approach
- Evidence-based learning and improvement

Microlearning that is Scientifically Proven by Science, Practice and the Market

Make It Easy

Break training content into bite-sized, scenario based challenges

Make It Stick

Use clinically proven spaced-education methodology to improve knowledge and skills

Make It Mobile

Reduce training costs and reduce monitor time off-site

Make It Engaging

Keep monitors engaged with game mechanics, peer socialization and personalized coaching

Make It Measurable

Measure proficiency and identify gaps to inform further training initiatives

Qstream's scientific approach has been validated in more than 22+ randomized control trials to boost performance and durably change behaviors. Developed at Harvard Medical School, Qstream is the only mobile microlearning platform scientifically proven to increase long term knowledge retention by 170% and change behaviors that improve job proficiency up to 35%.

Unlike traditional corporate training programs, the Qstream mobile microlearning app delivers scenario-based, precision learning in just minutes a day, and within the daily flow of work. Knowledge-intensive and highly regulated industries such as pharmaceutical, medtech, biotech, and healthcare organizations use Qstream to improve recall of critical information and identify individual proficiency gaps so managers know who, what and when to coach.

Qstream In Numbers

17% average proficiency improvement

93% average engagement

600+ customers

50m+ questions answered

Used By

14 of the top 15 pharmas

7 of the top 10 medtechs

4 of the top 5 medical schools

4 of the top 5 US hospitals

Learn why a global biopharmaceutical leader chooses Qstream Microlearning for clinical research education to reduce risk and improving site monitor proficiency.

Request a Demo

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