

Appreciated & Informed: How Site Engagement Technology Improves Protocol Adherence and Ensures Clean Trial Data

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It's Monday morning at a rare-disease trial site somewhere in the United States and a site director is welcoming her third new hire over the last six months. As the new study coordinator begins her day she's confronted with a large stack of clinical trial protocols for the site's 14 active trials. After a few minutes of flipping through and scribbling notes, she's interrupted and asked to help screen a patient who's shown up outside of his visit window, for a trial the investigator isn't familiar with. Is this study coordinator adequately supported to ensure proper protocol is followed for every procedure, or that all data were captured accurately, on each trial?

Unfortunately, this scenario, and others far more frightening, are not uncommon. Given

high turnover and competing priorities, a lack of a true site engagement strategy can have unintended consequences such as protocol deviations, unclean trial data, and costly delays. At DrugDev, we believe all technology providers, no matter which challenge they are solving, have a responsibility to ease site burden, not add to it.

In our experience, site engagement technology is one of the best ways sponsors and CROs solve these challenges. The following best practices, learned from working with thousands of sites using the DrugDev Spark™ clinical operations suite, will ensure sites remain engaged throughout the trial, with great attention to protocol adherence and data management issues.



What is Site Engagement and How Can It Help?

Site engagement technology is any platform, tool, or portal that sponsors and CROs employ to provide sites with accurate trial information, cultivate a community with a shared sense of ownership, and deliver relevant clinical education. When properly executed, Site engagement creates an environment that makes sites feel appreciated and informed. This leads to better adherence, better data, a sense of accomplishment, and less work. Specifically, DrugDev has seen the lowest protocol deviations and unclear data when site engagement...

1. Educates in an engaging way
2. Provides continual and relevant information
3. Creates a community for all trial sites and the sponsor

4. Allows sites to understand how they're doing in the big picture
5. Answers questions quickly and easily
6. Employs an effective user interface
7. Simplifies the everyday work of sites

If that sounds like an excerpt from a resume, it's because the best site engagement tools are able to function similarly to a standout employee - one that sponsors can count on to meet and fulfill certain needs. And just like employees, the best way to keep high-performance sites engaged is to focus them on their goals, provide the training they need, challenge them, leverage performance metrics, and acknowledge their successes. Let's look at how site engagement technology, whether on DrugDev Spark or another clinical platform, can accomplish these objectives and more.

Use a Modern Multimedia Training System

In a heavily regulated industry like life sciences, it's understandable that people can become fatigued by all the training and retraining required in a business setting. At a clinical site, however, training at an Investigator Meeting is often their first chance to understand a trial, dive deep into the protocol, learn how to use systems they'll rely on, and understand the impact and intended benefit for patients.

Unfortunately, sites are overwhelmed with information at the IM, and many people who will work on your trial during its lifecycle will join after the IM is completed. Further, the trainings delivered aren't often prioritized to be engaging. Rather than simply checking a required box, sponsors and CROs should approach training as their first opportunity to improve sites' quality of life and reduce protocol deviations.



Pro Tip Lesley says...

In our experience, the best feedback we've observed comes from sites who thought that sponsors' training, if you can believe it, was actually... fun. At DrugDev, we've seen sponsors employ an engaging mix of video, sound, animated slides, and in some cases even games. These types of training were not only engaging, but also extremely informative. They took the time to explain the "how and why" for each decision the sponsor made, including showing the reasoning for each of the different protocols that sponsors developed.

Examples within the DrugDev Spark system of training that's more engaging and interactive through use of audio and video.

It also enables further training and re-education that sponsors disseminate over the course of the trial as procedures are updated and as new staff join the study. The same is true for sites with only a handful of patients, as they don't have that daily activity level that

keeps them naturally engaged. For these sites, further training is a great way to re-inform, re-educate, and re-energize to ensure they are prepared when patients do arrive and trial activities are required.

Provide Relevant, Specific, and Actionable Information

The best site engagement tools work because they create a single, trusted source of news for sites - and most importantly, they provide actionable information to keep sites on track with activation, study tasks, and data query resolutions.

able to move from update to action simply by clicking a hyperlink contained within the message.

It's essential that sponsors utilize site engagement's ability to provide targeted information to entire networks, subsets of networks, or individual personnel to the best of their ability. This is the key reason that sites come to trust and appreciate Site engagement tools.

Other times, bulk messages make perfect sense, like when the study protocol has been updated or clarified, and all sites need the same information immediately.

To help with keeping data clean, for example, DrugDev has seen sponsors have great success by using site engagement to monitor sites, pushing daily, tailored communications to specific personnel. These communications were helpful in remedying issues and answering questions because they were

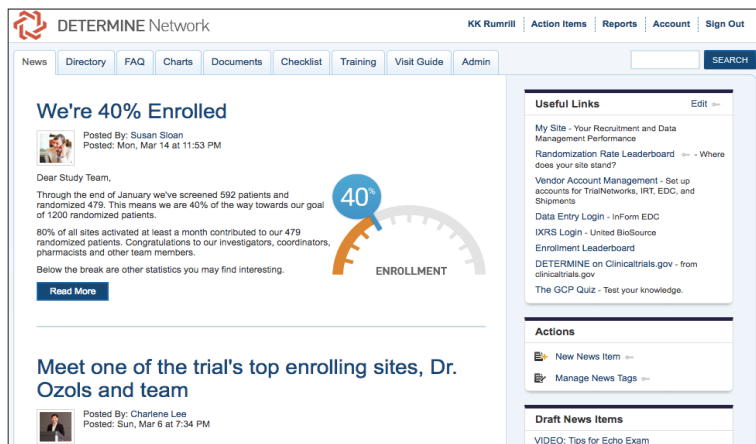


Pro Tip
Dani says...

If a sponsor sends in a question, comment, or concern that leads to a study clarification, FAQ update, or other gain, thank them publicly or privately within the platform to let them know you're appreciative and that their work is appreciated.

Sponsors and CROs have success in adherence, clean data, and other trial tasks when they take an “investigator and coordinator needs” approach for any and every communication. The key is to make

each email relevant for the person receiving it, deliver the information (and only that information) they need, and make it as easy as possible for them to take immediate action on it with just a few clicks.



DrugDev Spark's Site Engagement dashboard is a great place for sponsors to place information relevant to all study teams.

Here, sites are shown the overall enrollment for a study while receiving a direct look at the practices of a top-enrolling site in the trial.

Create a Community

One of the best feelings for sites when working in clinical trials is the sense of pride, community, and pending accomplishment first experienced during the initial investigator meeting. During the IM, everyone understands why they're there, what they're doing, and the effect they can have on the greater good. However, in many trials, that sense of community that's created during the initial meeting can wane over time, especially in longer trials and when facing frequent staff turnover.

When employed effectively, sponsors and CROs use site engagement to foster and cultivate that sense of community by showing sites how they're doing compared to their peers. This is accomplished using leaderboards for critical goals (e.g. enrollment, retention, query resolution), by providing sites with relevant updates on the progress of the trial, awarding achievement badges to the entire network, and taking the

time to highlight best practices and stories that comes from sites themselves.

The effects of these measures, both qualitative and quantitative, may be the most undervalued benefit of clinical technology. DrugDev clients regularly report global sites displaying better morale, renewed energy and motivation, and most of all, fewer errors. Even better, these small updates and encouragement are only a few clicks away.



Pro Tip Lesley says...

Posting best practices from other sites, educational interviews from other site staff, and tours of other site facilities and practices is a great way to spark imaginations and remind sites that they're all connected and working towards a common goal.

Encourage Friendly Competition

Principal Investigators are watching the leaderboards. It's human nature – no one wants to be doing “just ok” compared to their peers, and PIs want their site to be at the very top. That's why leaderboard emails routinely score the highest open rates specifically among PIs.

Sites who are provided with leaderboards or other indications of their performance rankings routinely take action. These leaderboards can be created and crafted for any issue, including randomization frequency, data upload leaders, sites asking the most questions, sites with the least deviations, and more.

Adding to that, we've seen sponsors employ site engagement technology in a friendly and efficient manner by sending statistics or leaderboards to only those who may need a boost. This has proven to be an effective approach in getting sites motivated, while refraining from shining the spotlight too brightly on sites who may be underperforming.

Badges are another fantastic way to encourage friendly competition, reward good behavior, and inspire hard work. Site personnel feel encouraged when awarded

public badges on the site engagement platform. This is especially true when coupled with personal notes from the study team thanking them for their hard work and accomplishments.

Leaderboards and badges are both effective ways of showing sites how they are doing compared to their country and global peers, praising sites in a positive and stress-free manner, and garnering friendly competition and inspiring increased performance.



Pro Tip Dani says...

Sponsors and CROs have been creative with badges, running challenges focused on data management or other trial goals. In one example, sites received a badge worth 100 points for having no data queries open after 15 days. At the end of the challenge, a donation was made to a charity of the winning site's choice in their name. This was one of the more enjoyable methods of ensuring clean trial data.

Jean-Luc Clermont
Award Badge

Role in Trial Principal Investigator Site 0018 (Dr. Laurent)

Contact jclermont@ndemo.com

Address 5000, Rue Belanger
Montreal, QC H1T 1C8, Canada

Badges Received

10 Patients Enrolled for March 2015
to Site 0018 from Charlene Lee
What a milestone!

Here are example badges provided to site personnel during a clinical trial in DrugDev Spark. Badges are a simple and effective way to acknowledge a site's hard work while saying “thank you.”

Provide Sites with Instant, Practical Answers

Have you ever scoured a FAQ (frequently asked questions) document, only to discover your question is answered thoroughly? Were you thrilled? Were you more likely to return to it later?

Sites are busy, and they only spend a small portion of their day on trial activities. So, when they have a question, they need an answer immediately, before they're off to the next thing. Making it as easy as possible for them to get the information they need, the moment they need it, is another way site engagement technology helps ensure procedures are fully understood and properly followed.

DrugDev's experience has shown that using site engagement to answer questions before they're asked, or quickly update it to answer new site questions, is an effective way to build trust towards the tool. And, once again, it helps increase protocol adherence and clean data.

One effective way to create trust is by providing detailed FAQs. Study teams know some of the tough and common questions they'll receive about their protocol. The FAQ is an excellent place for those answers to live. In other instances, sponsors may be asked questions they weren't expecting. In this case, we've seen success when sponsors provided clarification for the entire network of sites, and then, of course, updated the FAQ. Odds are, if one site is asking the question, there are many others who are thinking it as well.



Pro Tip Lesley says...

Use site engagement to monitor which protocol items are confusing by identifying which questions in the FAQ are viewed the most. From there, we've seen sponsors address those issues by sending updates and communications, and revising the FAQ itself.

The Frequently Asked Questions (FAQ) section of the site engagement platform is an excellent way to answer common site questions in advance, as well as provide sites with clarifications and answers around new questions.

The screenshot shows the Determine2 Network website interface. At the top, there's a navigation bar with 'News', 'Directory', 'FAQ', 'Documents', 'Training', 'Visit Guide', 'Screening Log', and 'Enrollment'. The 'FAQ' tab is selected. Below the navigation, there's a search bar and a 'SEARCH' button. The main content area is titled 'Frequently Asked Questions' and is divided into several sections: 'General', 'A. AEs/SAEs Assessment', 'B. Drug Administration', 'C. Electronic Data Capture (EDC)', 'D. Inclusion/Exclusion', 'E. Procedures', 'F. Study Design', and 'H. Visits'. Each section contains a question and a brief answer. On the right side, there are two sidebars: 'Most Recent Questions' and 'Most Viewed Questions', both displaying a list of questions with their respective dates and view counts.

Simplify the User Experience by Minimizing Clicks!

A clean, simple, and effective user interface (UI) is arguably the most important requirement for a proper site engagement platform – because if it adds burden, sites aren't going to use it as they should. Teams can put forth all the effort in the world towards creating a beautiful, educated, informative experience. But, if that experience requires too many logins and is clunky to maneuver, then sites will be less likely to trust and use it. While there is no one right UI for everything, DrugDev recommends that each and every site engagement UI be searchable and actionable throughout the entirety of the system. This means that any document, clarification, or piece of guidance can be found at any time through the search bar. It also means that sites can easily

navigate from one area to the next with just a few clicks. After all, sites cannot act on a communications, clarifications, or issues, if they cannot figure out how to navigate the system.



Pro Tip *Dani says...*

Make sure the site engagement platform you use can index all documents in its search feature. DrugDev Spark, for example, indexes the text of all news posts, PDF study documents, FAQs, training modules, etc. to provide Google-like search results the instant sites need them.

The Importance of Search

In 2018, search is a given expectation that every user has when interacting with a computer, tablet, or phone. It's important that sponsors make the ENTIRETY of their Site Engagement platform searchable. Search is typically the first tool users turn to when they need to find important information. Thus, any platform, or area within a platform that lacks search helps foster an environment that can lead to non-adherence, unclear data, or worse.


Use Tools to Create a Simple Work Life

It's no longer enough to provide sites with technology solutions and hope for the best. In addition to their intended function, it's also critical that any technology implemented is focused on making a site's work life easier.

Thankfully, Site Engagement provides sponsors with several different tools they can employ such as...

Visit Guides: Visit guides not only take away the hassle of scheduling visits, but also display the objectives and goals for each visit, allowing sites to follow along with study specific protocol at the time of each patient visit.

FAQs: FAQs provide clarifications and answers to tough or common questions.



Document Library: A searchable document library that sites can trust to find the exact document they need, at the time they need it. DrugDev recommends placing each and every document for the trial in the library, and updating them when appropriate. Sponsors with security concerns can rest assured knowing that many site engagement platforms offer different levels of permissions on a per-document basis, meaning that access is restricted to only the appropriate personnel.

News, Training, & Information Updates: Most site engagement tools offer a variety of ways to this. For full-scale, mass announcements, DrugDev has helped sponsors put information directly on the portal homepage, while updating the

FAQ. For more tailored and personalized messages, sponsors have employed a variety of different methods such as email blasts, direct messages.

Directories: There will always come a time during a clinical trial when sites will need to speak with a human instead of technology. In these instances, providing sites with a searchable, sortable, easy-to-use directory is paramount in keeping sites happy, data clean, and reducing protocol deviations.

These tools, when coupled with the tips presented earlier can come together to remove some of the administrative burden of every day trial life. Once again, this all adds up to create an environment that's prone to better data, and less error.

Bringing it all Together

As an industry, we all understand the importance of protocol adherence and clean data. Mistakes in these areas can adversely affect the safety of our patients, require more work down the line, and bring costly delays to trials. And while the industry will never eliminate human error, it's up to everyone in the industry to help mitigate it at all costs.

For DrugDev and our clients, site engagement has proven to be an effective mitigation tool that improves the quality of sites' lives. After all, every chance that a sponsor has to...

- Request an action,
- Boost a sites morale,
- Guide personnel along,
- Resolve an issue,
- Answer a question, or
- Provide a critical update

...is a chance to reduce the likelihood of error, and improve the lives of sites and patients alike.

About DrugDev

The DrugDev clinical operations suite is the industry's most comprehensive unified solutions platform – comprised of innovative technology and expert services proven to add value on thousands of clinical trials. From planning through closeout, our solutions are rigorously tested and improved by sponsors, CROs and sites of all sizes, in more than 60 countries. To learn more, request a demo at www.drugdev.com.