Case Study

Global Pharma Company Dramatically Improves Collaboration, Communication, and Compliance in Trials

IQVIA Investigator Site Portal: An Enterprise Implementation

Situation

A Top 5 global pharmaceutical company wanted to streamline communications and ease the burden of manual tasks and repetitive training for sites. After evaluating several options, the company deployed IQVIA Technologies' Investigator Site Portal (formerly DrugDev) for complete study conduct, utilizing its purpose-built Learning Management System (LMS), Document Exchange, and Site Engagement modules.

- Nearly 105,000 site staff have now used the Investigator Site Portal across more than 280 trials sponsored by this pharma company
- More than 32,000 of these unique site users work in two or more study portals
- More than 35,000 sponsor-level users actively use the system to support multiple studies with a single sign-on

Learning management system

The LMS of the IQVIA Investigator Site Portal now provides this sponsor's clinical training department with powerful capabilities to develop and run a fully digital program that leverages content company-wide, eliminates redundant training, and streamlines compliance audits.

- More than 4,100 cross-trial courses are now available in the company's training catalog
- Nearly 1.6M training records have been captured across this sponsor's studies

Site engagement and document exchange

The Site Engagement and Document Exchange modules make it easy for the sponsor to communicate with all sites at once — or correspond with a particular set of sites based on characteristics such as geography, trial completion parameters, or responsiveness to prior correspondence.

- 25,000 documents uploaded by this sponsor have been downloaded by sites nearly 300,000 times
- 5.3M study updates and automated task notifications have been distributed to site users

Agile product development

Responsive support

140k **ACTIVE SITE AND SPONSOR USERS**

across 280 trials within 3 years

MORE THAN

30% **OF UNIQUE SITE USER ACCOUNTS**

work in two or more study networks — indicating significant efficiencies being gained in the site community

Site-first tools such as patient visit guides and centralized pre-screening logs support staff in patient enrollment and protocol adherence. Site Engagement has proven to be invaluable in keeping sites up to date on nearly a daily basis during the COVID-19 pandemic.

A recent survey of a representative sample of site and sponsor users showed that it is ranked as a top technology solution in its clinical technology stack:

- 90% of users say it is easy to use, ranking it as the easiest system to use in the company's entire Tier 1 technology portfolio
- 97% of users say they feel well supported in using this system
- Users rank it as the most stable system in the company's technology portfolio, with the fewest number of operational issues reported in the last six months

"Investigator portals have been an essential tool for us in support of communications with investigators and site staff during COVID-19. This has enabled us to maintain a positive relationship with investigators as we need to quickly exchange information on this rapidly evolving situation. We are also able to utilize the learning management system within the portal to initiate new training remotely in an auditable fashion."

— VP, Clinical Insights and Experience

Challenge

When launching a clinical trial, securing the right research sites is critical to success. The most desirable sites are run by leading investigators and staff in the therapeutic area to be studied and are able to reach more potential participants, which is key to meeting patient recruitment goals.

However, as therapies are becoming more targeted, the number of drugs being studied is increasing. Investigators have a finite capacity to run trials, meaning the most in-demand sites will often have their pick of projects. If sponsors want their studies to be chosen and begin recruiting patients quickly, then they need to provide tools that enhance the trial experience and give site staff more time to focus on patient care.

Always striving to deliver more value

This Top 5 global healthcare company continually seeks digital innovation to drive its diverse array of pharma, biotech, med-tech, and consumer health businesses, as it focuses on bringing life-saving therapies to its diverse patient populations. Clinical development platforms must enable sponsors to deliver value to business units.

In 2017, the company's study leaders were looking for a technology platform that would continue to enhance its reputation as a sponsor of choice to investigators across the globe. To do that, they knew they needed to eliminate the duplication of efforts that can be burdensome for sites as well as site-facing sponsor staff, streamline site communications, and improve the training process.

The key issues the sponsor wanted to address include:

- A simple and consistent way to communicate with sites and share clinical trial documentation
- A global training platform that could leverage content, track compliance across trials, and reduce repetitive trainings — a key source of frustration for site staff
- A one-stop shop of tools to help sites collaborate and do everyday tasks more efficiently and adhere to the protocol more effectively
- Consistent reporting and transparency across studies and sites to identify opportunities for targeted improvements in trial management

Solution

After reviewing and piloting high-profile technologyoptions in the industry, the pharma company selected IQVIA Technologies' Investigator Site Portal (formerly DrugDev). The solution provides the sponsor with a single platform to collaborate with all its trial sites and manage every aspect of training, document exchange, and communication to reduce administrative burden on sites and clinical research associates (CRAs), as well as measure results and meet compliance goals.

The pharma company used a staged approach to introduce the technology to sites and build competencies in-house within Clinical Operations.

Phase 1 — Introducing the technology

In the first several studies, the sponsor introduced Site Engagement and Document Exchange to sites and CRAs, relying on IQVIA Technologies' implementation and support team to set up each trial network and associated system integrations, create and post newsletters, build folder structures for clinical trial documents, and generate the FAQ repository.

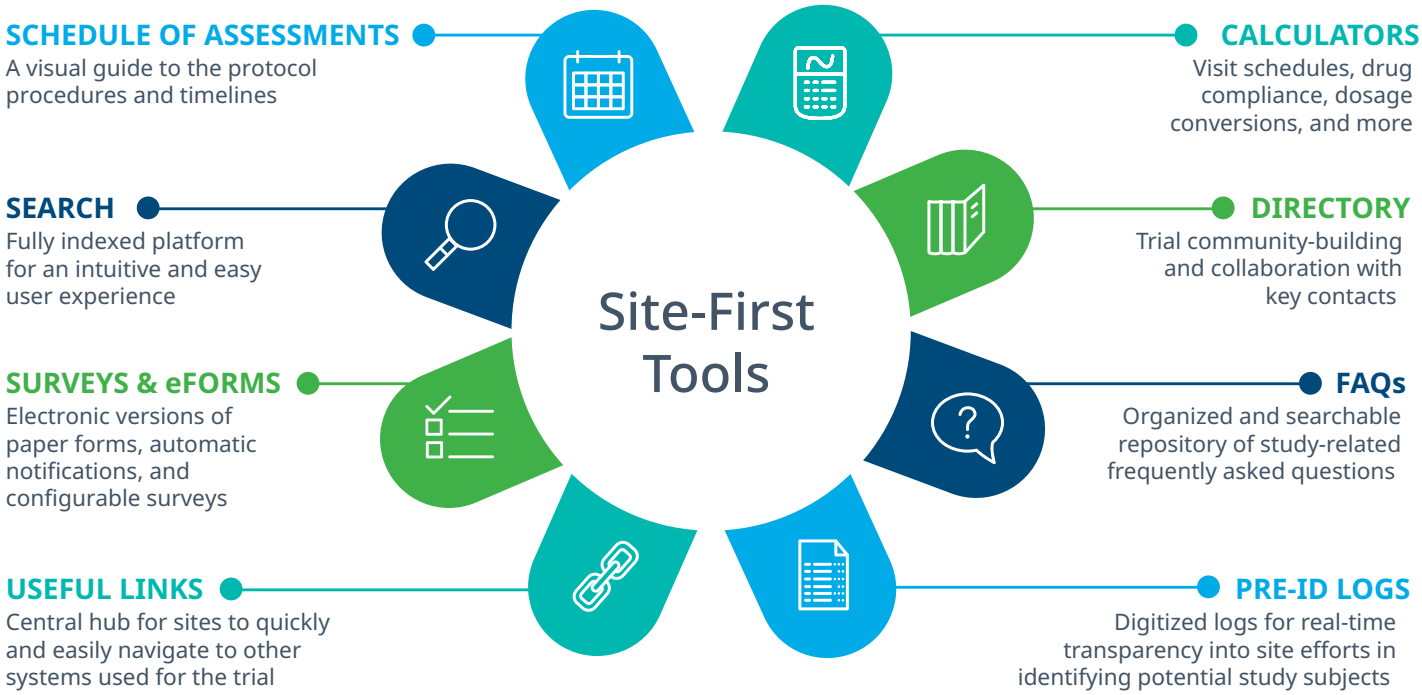
Phase 2 — Adopting an enterprise model

The flexible, intuitive interface of the Investigator Site Portal enabled the sponsor to become proficient in system administration and make it the standard for all studies across the company and around the world. Once IQVIA Technologies configures the tenant, creates URLs for the trial, and builds the protocol-driven visit guides, the sponsor is self-sufficient.

KEY FEATURES OF THE DOCUMENT EXCHANGE MODULE

- 21 CFR Part-11 compliant
- Well-defined folder structures
- Deep text search
- Google-like results
- Role-based access
- Bulk uploads
- Dynamic distribution lists
- Usage reporting

FIGURE 1: STUDY CONDUCT EFFICIENCY TOOLS—MAKING LIFE EASIER FOR SITES AND STUDY TEAMS WORLDWIDE



Phase 3 — adding learning management

IQVIA Technologies' LMS was implemented in this phase on a trial-by-trial basis to provide sites and study teams with a single source for training, knowledge assessments and reporting. Courses across the company were consolidated into the LMS to enable distribution across sites based on task responsibilities, then tracked for completion and compliance.

The sponsor also took advantage of digital delegation logs and e-signature to replace the paper version, making it easy for principal investigators (PIs) to add staff as delegates.

Phase 4 — embracing cross-trial training

With the value of IQVIA Technologies' LMS clearly established, the sponsor implemented the newest crosstrial training features. They developed a centralized training catalog across all countries, therapeutic areas, roles, and task responsibilities, from which courses are pushed to individual studies.

Cross-trial credit is now available to learners who already passed a course for a previous study, saving precious time during study start-up. Version control ensures learners are offered the most up-to-date training.

Result

The Investigator Site Portal has transformed the culture for this pharma company's entire site network. The LMS, Document Exchange, and Site Engagement modules make it easy for the sponsor to communicate in an organized, measurable way with thousands of sites across the globe and provide a one-stop shop for all communication and training activities related to every study.

In just three years since implementation, the Investigator Site Portal has become one of the most popular systems in this sponsor's clinical technology stack. The interface is so intuitive and simple to use that investigator sites require virtually no training to get started. That's why it has been enthusiastically embraced by study teams and investigator sites alike.

KEY FEATURES OF THE LMS MODULES

- Centralized training catalog with the ability to push specific courses to individual studies
- Digital delegation logs with e-signature to replace the paper delegation process
- Training courses automatically distributed based on task responsibilities, including those assigned through the delegation log
- Ability to grant credit to site and sponsor users for required trainings already completed for previous trials
- Tracking of both the course and the version completed

A collaborative study environment

- More than 105,000 site staff* have actively used the Investigator Site Portal to conduct nearly 280 trials* in 78 countries* for this sponsor
- More than 35,000 sponsor-level users* actively use the system to support multiple studies with a single sign-on
- More than 32,000 sites users* work in two or more study portals — more than 30% of total user accounts — a key indicator of the efficiencies being gained as more and more studies are deployed in the IQVIA Investigator Site Portal
- 5.3M study updates and automated task notifications have been distributed to site users

A collaborative study environment

- Nearly 25,000 documents* have been uploaded by this sponsor
- Nearly 300,000 documents* have been downloaded by sites

*As of August 2020. These numbers increase monthly.

The Benefits

The IQVIA Investigator Site Portal has significantly reduced the administrative burden on CRAs around the world, enhancing this company's reputation as a sponsor of choice. At the same time, it has increased efficiencies and decreased costs in several key areas:

- Sites save time with self-service access to documents, cross-trial training credits, digital delegation, and e-signature
- CRAs spend less time answering questions from sites and mailing/emailing documents back and forth
- Quality and training staff are more efficient with a centralized course catalog across all studies
- Investigators are continually engaged, informed, and motivated, keeping this sponsor's studies top of mind and helping them succeed in all that is asked of them
- Site staff are supported by useful tools such as pre-screening logs and patient visit calculators, saving them time and reducing protocol deviations

Site satisfaction

Site users appreciate all the ways the IQVIA Investigator Site Portal helps them do their jobs more efficiently. They rank it as a top solution provided by this sponsor in many categories:

- It is one of the highest rated systems in the company according to the company's own internal surveys of site user samples
- Users rank it as the most stable system in the company's technology portfolio. It has had the fewest number of system breakdowns and operational issues reported in the last six months
- 90% of users say it is easy to use, which ranks it as the easiest system in the company's entire Tier 1 technology portfolio
- 97% of users say they feel well-supported in using this system

*As of August 2020. These numbers increase monthly.

Cross-trial training

- More than 4,100 cross-trial courses* are now available in the company's training catalog
- Nearly 1.6M training records* have been captured across this sponsor's studies

Benefits during COVID-19

Since the COVID-19 pandemic shut down trial sites across the globe, sites have had to rapidly shift to telemedicine visits, remote monitoring and other virtual trial elements. This sponsor is leveraging the LMS and site engagement modules to accelerate the transition and ease disruption to ongoing and newly launched trials.

An Agile Platform for Continuous Improvement

This Top 5 pharmaceutical sponsor is an innovator — not only in drug development but also in the application of digital technologies to solve problems. That's why the company's partnership with IQVIA Technologies has yielded so much value to the clinical development organization.

Continually evolving as an agile product, the Investigator Site Portal delivers updates and new features more than monthly. Future enhancements include extending single sign-on functionality to sites, advancing the user experience, and enabling deeper analytics and reporting.

About the IQVIA Investigator Site Portal

The IQVIA Investigator Site Portal is a collaborative site-facing solution for complete end-to-end study conduct. Delivered in either a full-service or softwareas-a-service model, the solution consists of modules and tools that make life easier for sites and help the industry complete more trials successfully.

The Investigator Site Portal is part of IQVIA Technologies' Digital Site Suite under its Orchestrated Clinical Trials umbrella, with solutions that increase transparency, improve communications, and reduce administrative burden for all clinical trial stakeholders.

Orchestrate Outcomes

About IQVIA Technologies

IQVIA Technologies develops purpose-built solutions to enable life science organizations to orchestrate better outcomes across the entire product lifecycle.

IQVIA TECHNOLOGIES

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