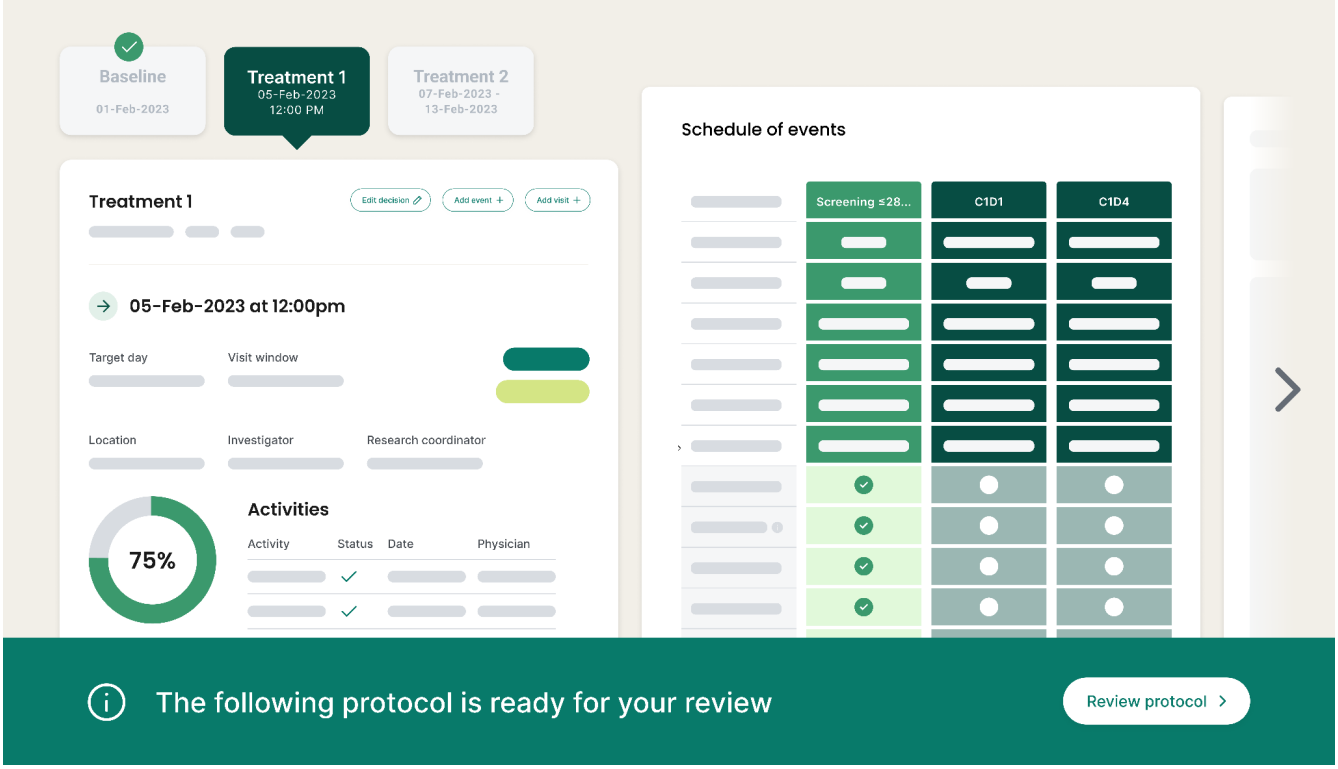
verily viewpoint

Site CTMS

Protocol Digitization: What exactly is this transformative CTMS feature?



Contents

Introduction – Overcoming research challenges through a proprietary, protocol-transforming CTMS feature

Certain clinical research challenges are not news to study sites. They feel the weight of this ever expanding, ever evolving field that's imperative for critical medical and science discoveries. Indeed, each year the clinical trials market grows 5.7%*[1], while the available research workforce dwindles.[2]

This imbalance only compounds the challenges study teams already cope with, such as duplicative or disjointed workflows, tech overload from clunky legacy software systems and tedious, time-consuming manual workflows, including executing against PDF, or "paper", protocols.

Clinical trial demand far outweighs the workforce supply

The answer to challenges in clinical research isn't a simple one. However, clinical trial management system (CTMS) software can solve some operational barriers for some site teams. Even so, many enterprise-research site customers are frustrated with current, in-market CTMS options.

Verily Viewpoint Site CTMS (formerly SignalPath by Verily), is an advanced CTMS and a holistic solution for sites to help meet research demands, while alleviating gridlock for all stakeholders.

With Site CTMS, teams leverage user-friendly features and market-leading innovations that simplify and streamline paths to discovery, including this proprietary technology: **protocol digitization**.

What exactly is protocol digitization?

Sites are often bogged down by the daunting task of building, running and analyzing a study as directed by the protocol. And they may be executing these essential tasks by way of a PDF (or “paper”) protocol.

The expertise, time, effort and budget required to achieve all of this is often immense, not to mention creating a mental and morale strain on staff. Compounding all these stressors with increased study volumes, limited workforce and turnover, sites may not realize that it *doesn’t have to be this way*.

With Site CTMS’s proprietary protocol digitization feature, PDF protocols are accurately and efficiently ingested and digested, turning pages and pages of criteria, logic, steps and data into a digital master study translation. Once digitized, Site CTMS powers and propels all clinical and financial workflows for every consented participant.

This power also extends beyond managing a study’s schedule of events. Through protocol digitization, the schedule of events, inclusion and exclusion criteria, randomization and other critical information are pre-configured and automated within our CTMS by our tech and teams before a study goes live. In short, it simplifies and it streamlines.

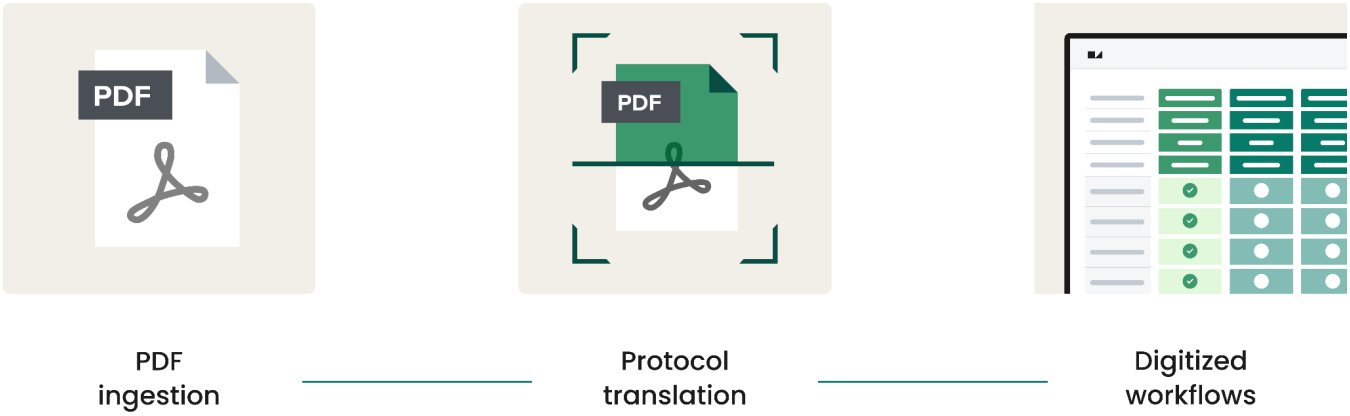


Figure A. With Site CTMS, there’s a better way to protocol. Sites are liberated and enabled to work on other tasks via our tech and teams transforming PDF protocols into digitized workflows.

How does protocol digitization work?

The technology- and team-driven process for protocol digitization is a simple, seamless experience for research clients that consists of four basic steps:

1. Clients submit their PDF protocol
2. Site CTMS's tech and team digitize their protocol
3. Together, they conduct quality assurance
4. Clients review and grant final approval

Also, because Verily is a leader in healthtech innovation, much of the protocol ingestion and workflow configuration occurs within the CTMS software itself. For more quality assurance, expert teams also assist to ensure clients receive timely, accurately digitized protocols.

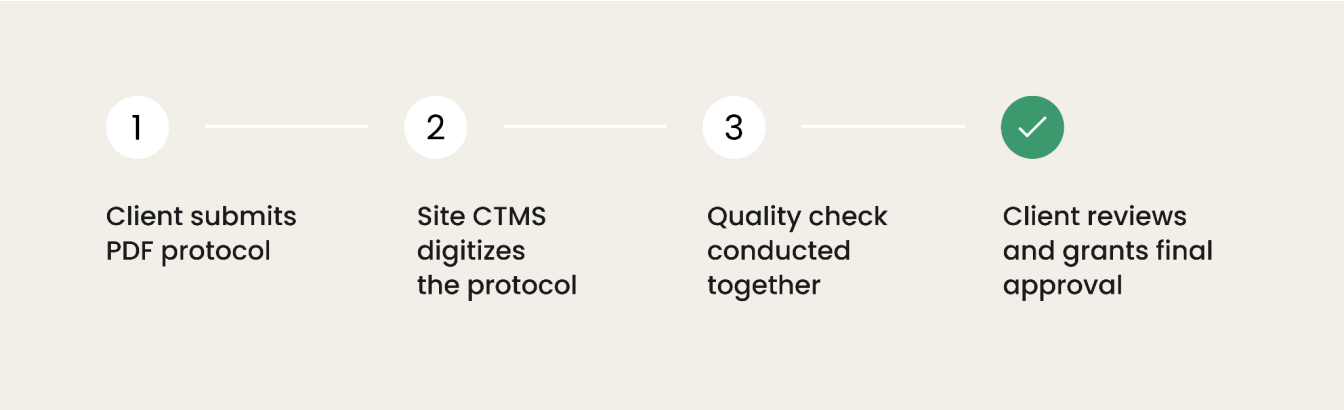


Figure B. Steps to protocol digitization are simple and seamless for clients.

What is the outcome of protocol digitization?

Once digitized, study teams can easily view, manage and adjust studies, including elevated, organized views of activity schedules and more within Site CTMS. Figure C., D. and F. demonstrate some of these post-configuration, efficiency-enabling features.

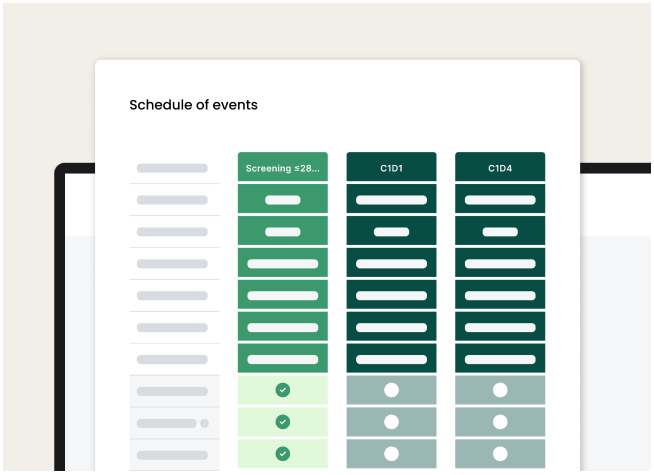


Figure C. Researchers can gain immediate, detailed schedule of events for participants

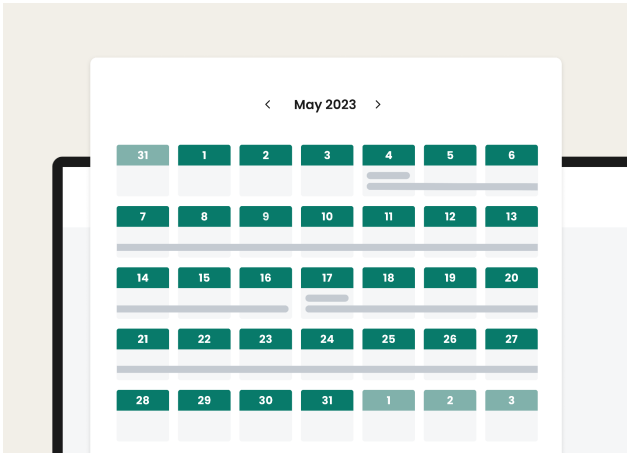


Figure D. Researchers can stay organized via calendar views for each study arm

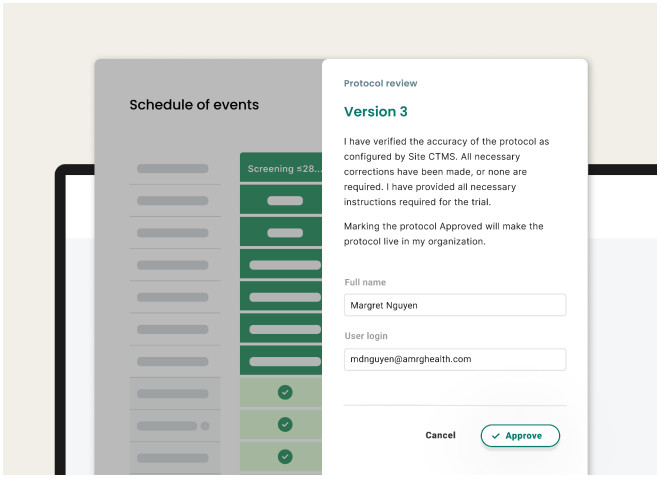


Figure E. Once digitized, teams can stay on track with optimal version control and revision tracking

How exactly is protocol digitization valuable?

Protocol digitization is a comprehensive digital translation of a study protocol. Because of this, its value transcends helping coordinators and clinical staff successfully execute intended procedures and activities, such as providing the pre, during and post steps to fully facilitate participant visits (although it provides this key feature, too).

Protocol digitization with Site CTMS adds value – from process improvements to research quality to actual monetary value and more – for all study stakeholders, aiding researchers, financial teams and site leadership. **Protocol digitization is also a standard Site CTMS feature, which means all clients reap the benefits.**

Value to researchers

When asked what fuels most researchers, many will say the research itself—the potential to make new discoveries and answer crucial questions. Protocol digitization supports a streamlined, simplified path to discovery that improves research quality and therefore, researcher confidence.

Operational efficiency drivers

May reduces manual tasks for start up and conducting studies

Can limit reliance on sponsors for tools and resources

Helps eliminate spreadsheets for workflows and logic

Fosters lower learning curves for launching and running studies

Quality improvement drivers

Supports diminished deviations in managing and performing activities

Helps prevents revision and versioning issues per one master translation

Helps ensure operational continuity, especially with staff changes or PTO

Value to finance teams

Even though sponsors pay study sites to conduct clinical trials and research, budgeting is essential to mitigate financial waste and misuse. *However, balancing the books isn't easy.* Through building of a single, easy-to-navigate translation, protocol digitization enables a clearer picture of study coordination costs and their true monetary implications for sites; aligning research and finance teams to more effectively analyze financials and plan budgets.

In addition, this enhanced alignment uncovers financial pitfalls, such as revealing areas of under- or over-budgeting, which aids teams, especially for budget negotiations of future studies. For example, researchers may identify an unmatched budget item for the schedule of events, leading to inadequate reimbursement. This learning informs more precise planning to better support the site's research-related financial competency going forward.

Value to leadership

Protocol digitization can help improve research productivity, quality, affordability and ultimately, staff retention. These collective values may ladder up to the leadership level, supporting more productive relationships with sponsors and enabling more educated executive decisions, such as taking on additional trials or expanding research capabilities.

Here's how:

Staff retention:

Taking protocol configuration tasks out of scope can reduce staff burden and repetitive tasks that often lead to turnover.

Cost containment:

Sites may limit costs incurred from additional hires or consultants for manually building workflows into other CTMS software.

Risks reduction:

Through centralizing activities and procedures, protocol deviations that may potentiate risks, errors and waste can be diminished.

Ops improvement:

Pre-configured workflows can facilitate quicker study launches, faster staff onboarding and easier coverage for leave or vacations.

With Site CTMS, there's a better way to protocol

As the volume and complexity of research increases, study sites must rely even more on innovative technologies to alleviate pain points that can slow down studies, drive away talent, increase cost, threaten output and more. But some tech doesn't deliver.

Site CTMS is an advanced, but **easy-to-use, solution** that performs as promised. And it's the ONLY CTMS with next-generation protocol digitization technology.

Instead of hiring new employees or burdening existing staff with onerous tasks, like operating against PDF protocols, clients who leverage Site CTMS work smarter, not harder; enhancing workstreams to help meet the growing needs of clinical research and boost job satisfaction.

Experience the innovation

Consider **Verily Viewpoint Site CTMS** to simplify and power your research operations. With advanced technology and next-generation CTMS features, your site can optimize and streamline management from study start to close through digitizing PDF protocols and other innovations.

View protocol digitization in action. **Request a guided demo** of this feature. Until then, **learn more** on how Verily Viewpoint Site CTMS can best support your research site.

Endnotes
*Annual compounded rate increase, global market
**Annual compounded rate increase, United States market
PTO = Paid time off

Sources

1. Bio-IT World Press Release: Clinical Trials Market Size USD 84.43 Billion by 2030. https://www.bio-itworld.com/pressreleases/2022/07/19/clinical-trials-market-size-usd-84-43-billion-by-2030
2. ACRP Special Report: An Assessment of the Adequacy of the Clinical Research Workforce. https://acrpnet.org/special-report-an-assessment-of-the-adequacy-of-the-clinical-research-workforce