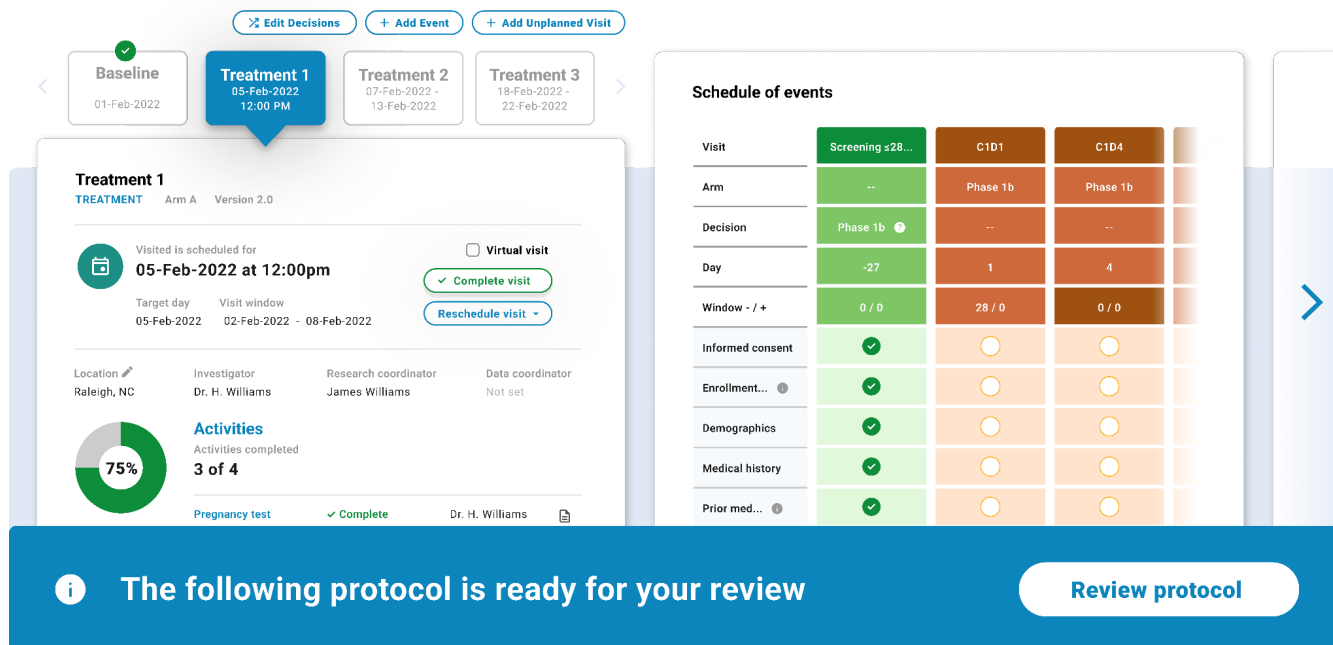


Protocol Digitization

What exactly is this transformative CTMS feature?



The screenshot displays the SignalPath CTMS interface. At the top, there are buttons for 'Edit Decisions', 'Add Event', and 'Add Unplanned Visit'. Below these, a timeline shows four treatment stages: Baseline (01-Feb-2022), Treatment 1 (05-Feb-2022 at 12:00 PM), Treatment 2 (07-Feb-2022 - 13-Feb-2022), and Treatment 3 (18-Feb-2022 - 22-Feb-2022). The 'Treatment 1' stage is selected, showing details for 'TREATMENT 1' (Arm A, Version 2.0). It includes a calendar icon, a visit scheduled for '05-Feb-2022 at 12:00pm', a 'Virtual visit' checkbox, and buttons for 'Complete visit' and 'Reschedule visit'. Below this, a 'Location' field shows 'Raleigh, NC', and an 'Investigator' field shows 'Dr. H. Williams'. A 'Research coordinator' field shows 'James Williams', and a 'Data coordinator' field shows 'Not set'. A 'Pregnancy test' status is shown as 'Complete'. A circular progress indicator shows '75%' completion, with 'Activities completed 3 of 4'. To the right, a 'Schedule of events' table is visible, showing visits, decisions, and activities across different treatment stages.

Visit	Screening ≤28...	C1D1	C1D4
Arm	--	Phase 1b	Phase 1b
Decision	Phase 1b	--	--
Day	-27	1	4
Window - / +	0 / 0	28 / 0	0 / 0
Informed consent	✓	○	○
Enrollment...	✓	○	○
Demographics	✓	○	○
Medical history	✓	○	○
Prior med...	✓	○	○

The following protocol is ready for your review [Review protocol](#)

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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 solutions.

[SignalPath by Verily](#), an [advanced CTMS](#), is a holistic solution for sites to meet research demands and alleviate gridlock for all study teams.

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

What exactly is protocol digitization?

Sites can be bogged down by the daunting task of building, running, and analyzing a study as directed by the protocol. And most are 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 the mental and morale strain on staff. Compound all these stressors with increased study volumes, limited workforce, and turnover. Sites may not realize that it *doesn't have to be this way*.

Through SignalPath's patented 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, our CTMS powers and propels all clinical and financial workflows for every consented participant.

Plus, this power extends beyond managing a study's schedule of events. Through protocol digitization, each study's 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.

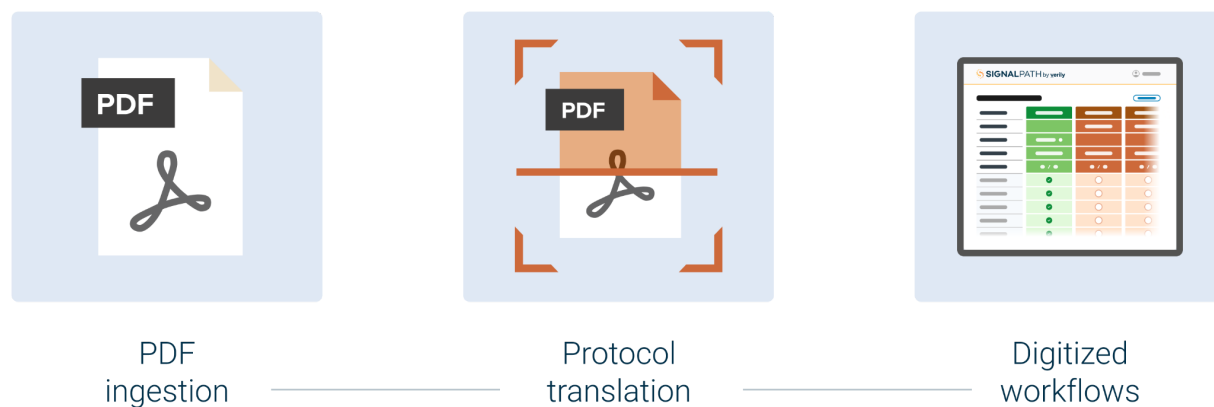


Figure A. With SignalPath by Verily, there's a better way to protocol. Sites are liberated and enabled to work on other tasks via our tech and teams transforming PDF protocols into digitized workflows.

How does protocol digitization work?

SignalPath's technology and 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. SignalPath digitizes 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 our CTMS software itself. For more quality assurance, our expert teams also assist to ensure clients receive timely, accurate digitized protocols.

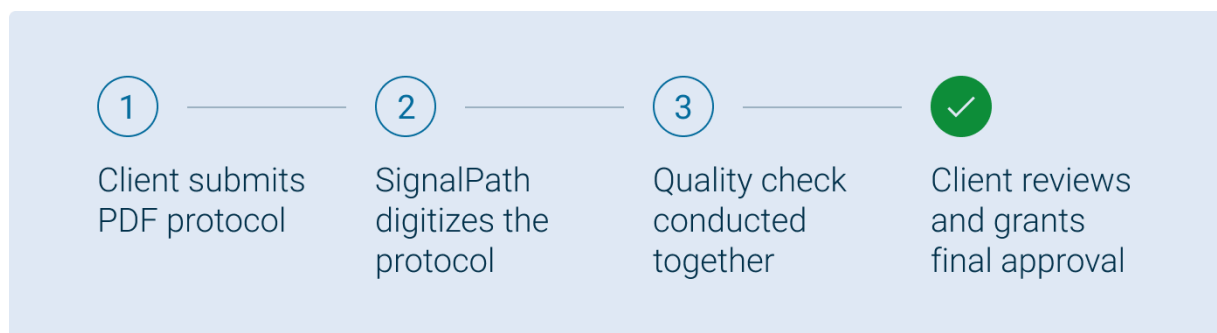
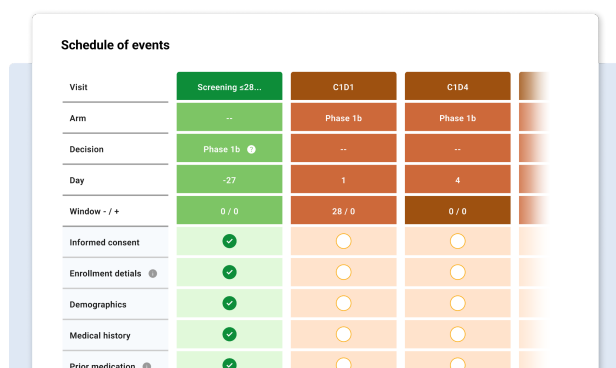


Figure B. Steps to protocol digitization are simple and seamless for clients.

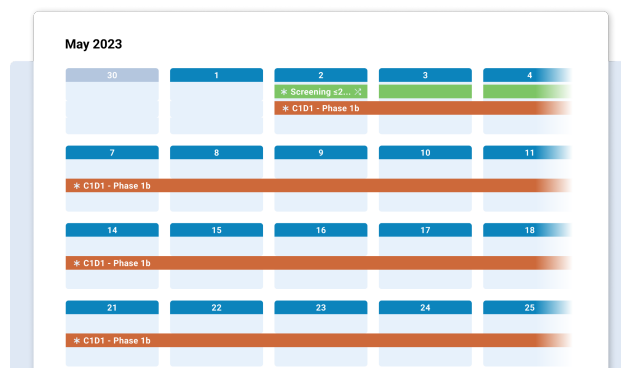
What is the outcome of protocol digitization?

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



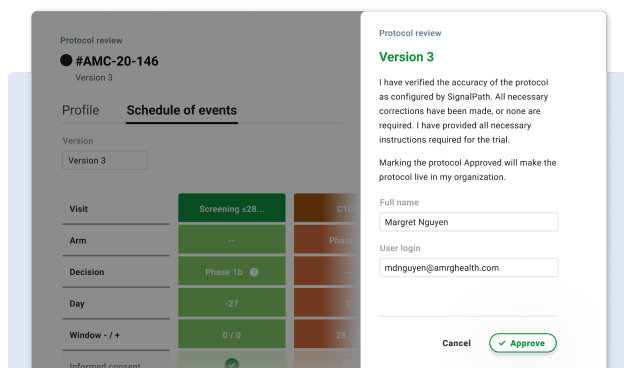
Schedule of events				
Visit	Screening s28...	C1D1	C1D4	
Arm	--	Phase 1b	Phase 1b	
Decision	Phase 1b ⓘ	--	--	
Day	-27	1	4	
Window - / +	0 / 0	28 / 0	0 / 0	
Informed consent	✓	○	○	
Enrollment details ⓘ	✓	○	○	
Demographics	✓	○	○	
Medical history	✓	○	○	
Prior medication ⓘ	✓	○	○	

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



May 2023				
30	1	2	3	4
		* Screening s2...		
		* C1D1 - Phase 1b		
7	8	9	10	11
		* C1D1 - Phase 1b		
14	15	16	17	18
		* C1D1 - Phase 1b		
21	22	23	24	25
		* C1D1 - Phase 1b		

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



Protocol review

#AMC-20-146

Version 3

Profile **Schedule of events**

Version 3

Visit	Screening s28...	C1D1
Arm	--	Phase 1b
Decision	Phase 1b ⓘ	--
Day	-27	1
Window - / +	0 / 0	28 / 0
Informed consent	✓	○

Version 3

I have verified the accuracy of the protocol as configured by SignalPath. All necessary corrections have been made, or none are required. I have provided all necessary instructions required for the trial.

Marking the protocol Approved will make the protocol live in my organization.

Full name
Margret Nguyen

User login
mdnguyen@amrghhealth.com

Cancel **Approve**

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 within SignalPath's 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 SignalPath 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 of new findings and crucial questions finally answered. 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 limits 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 its 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 both 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 via SignalPath's platform improves research productivity, quality, affordability, and ultimately staff retention. These collective values 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 the benefits of protocol digitization within the SignalPath CTMS may help site leadership:



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 SignalPath, there's a better way to protocol

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

SignalPath is an advanced, but [easy-to-use, CTMS solution](#) that truly 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 SignalPath work smarter, not harder; enhancing workstreams to help meet the growing needs of clinical research and boost job satisfaction.

Experience the innovation

Consider [SignalPath by Verily](#) to simplify and empower your research operations. Our next-generation CTMS with advanced technology and platform features optimize and streamline management from study start to close by digitizing your PDF protocols and other innovations.

View protocol digitization in action. [Request a guided demo](#) of this transformative feature. Until then, [learn more](#) about how SignalPath 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>