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Is Your Paper Protocol Really Fit for Purpose?

Why now is the time to transform your clinical trial protocol into real-time site engagement.

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Addressing the Elephant in the Room

There's an elephant in the drug development room.

It's a problem negatively impacting the advancement of clinical research on a global scale. It is responsible for the most frequent offending FDA (Food and Drug Administration) inspection citation, year after year.

Yet, no one really talks about this problem, which is deeply rooted in an incredibly inefficient and risky status quo. The problem, simply put, is the antiquated clinical trial protocol. Instead of an active hub of content and communication that drives clinical trial decisions, today's protocol is locked away. Most commonly it is a paper document in a binder or a paper-like electronic PDF - in both cases the protocol is inconveniently stored away from where it is needed the most.

Why is this a problem?

Well, for starters, not having constant and instant access to the protocol leads to mistakes. No one can be expected to remember every detail. So, unless study investigators, research nurses, study coordinators and others physically retrieve the protocol, they are relying on memory to make study decisions. Mistakes slow down drug development, increase safety risks to participants, and leave vulnerable patients without access to potentially life-saving treatments.

Study sponsors also miss any intelligence about their study when the protocol is a static document. Which sites are engaged with the protocol? What are they are looking at? What challenges are they facing? Physical documents and paper-like PDFs can't speak - they give no insights into who has looked at them, how often, and what they were looking for in the document.

In short, sponsors are blind.

Then there is the overworked and underappreciated study monitor. Clinical research associates (CRAs) are the connective tissue between research sites and study teams. Yet, as clinical trials become more complex, they aren't equipped with the right tools to really help their sites to make the best decisions. Frustrated and under resourced, CRAs are leaving clinical research in droves. This should be sounding alarm bells that something needs to change.

The irony is we are more dependent than ever on smartphones and digital devices to manage nearly every aspect of our lives. And we don't need to be tech geniuses. The latest information and real-time communication with friends, family, colleagues and others are always easily at our fingertips.

Daily Life is Digital. Why Not the Protocol?

We only need to look at how we operate in our day-to-day lives for clues on how digitally interconnected clinical trials can dramatically leap the industry forward.

Think about it. When you plan a trip, you go online to book everything - flights, hotel, car, and so on. Your boarding pass is scanned from your smart phone. Hotels have gotten so sophisticated that you don't even really need to check in – you can unlock your room with an app on your smart phone. There is an app for nearly everything you need for travel to support you on the ground and to familiarize you with your destination.

When it's time to make a dinner reservation, you have options at your fingertips with booking apps. Not only can you filter by the types of cuisine and proximity to where you are, you can make the most informed decision by also considering reviews of other patrons. It removes the uncertainty, especially if you are in a new place, by giving you everything you need to make an informed decision. You simply search, decide and book.

And what about getting from A to B? Are you more likely to take out a paper map or use a navigation app such as Waze for real-time guidance on the best route? Crowd sourced by other drivers' experiences, Waze will automatically reroute you around traffic, construction, or other unexpected hazards. While incredible advancements have been made with modern medicine, more can be done. A lot more. To achieve this, we need to address this elephant in the room that the protocol – the primary interface to the trial - has not kept pace with modern technology. Why are we willing to accept the status quo? Why do we still rely on static, disconnected protocols?

The Problem for Sponsors

Lack of Transparency + Missed Opportunity = Delayed Time to Market

No visibility into protocol engagement

Errors found too late to be remedied

Poor understanding of site challenges

In an increasingly competitive market, sponsors have three key success factors: quality of study conduct, speed of study operations, and assurance of patient safety. The study protocol is the key to performance in each of these areas.

Yet, providing a paper or paper-like PDF protocol creates three insurmountable challenges:

1. Reduced accessibility and usability at the point of care to safely conduct procedures accurately
2. Lack of visibility into questions or obstacles that are preventing sites from meeting critical milestones, such as recruiting the right patients on time
3. Difficulty attracting and retaining the best research sites

As a sponsor, paper and paper-like static PDF protocols do not allow you to see who is accessing the protocol, when, and for what reason. The answers to these questions could allow you to make valuable course corrections to keep your study on track, on time, and within compliance guidelines.

By issuing sites with paper or paper-like static PDF protocols hosted in a web portal somewhere, you are asking clinical investigators to do the impossible. You are asking them to freeze time during patient consultations to manually search through dozens of pages to query eligibility criteria, remember investigational product calculations and/or titrations, or check for appropriate management of adverse events.

Either that, or you expect clinical research staff to memorize the exact correct version of the entire protocol. Bear in mind that many investigators and site staff work across multiple trials simultaneously. In a world where it's common for this to be the case and for investigators to see between 20 and 30 patients a day, the existing process simply creates the conditions for a perfect storm.

Time-poor site staff don't have the hours needed to refer to paper protocols thoroughly during consultations or the time to call another trial team member and wait for a response. Instead, many rely on a "best guess" or existing knowledge from what may be an outdated version of the protocol.

This leads to deviations, violations, compliance failure – and now safety is compromised.

The thing is, as a sponsor, you won't be aware of site challenges with a study until they are too late to remedy. This is because paper protocols severely limit your visibility of how sites interact with the protocol. Reports from monitors lag by weeks or more, making it impossible to know if sites are engaged with the protocol, if they're experiencing issues with recruitment, or if they've noted early indications relating to potential safety issues.

This represents a costly blind spot. Retrospective identification is just too late for deviations and violations, compliance and data quality risks, and adverse effects of investigational products. It's just like this: a pan fire can't be extinguished with a fire blanket if it's not detected until the whole house is ablaze.

Sponsor reliance on email to share information with time poor CRAs and sites runs the very real risk of drowning in the daily email tsunami. How can you be sure that vital clinical trial information isn't getting lost in a CRA's inbox?

You can't.

Enrollment is another area made harder because of static protocols. Quick searches of current information while at the point of care ensure that physicians are enrolling the right patients and in accordance with the current version of the protocol.

A lack of accessibility to timely information limits familiarity with and understanding of the eligibility criteria.

And at site level, if a clinician is more familiar with the content of a competing protocol, why wouldn't they choose to err on the side of caution and recommend the eligible patient enrolls on the competing study? After all, it's the quicker, easier and less risky option. But in this scenario, sponsors lose eligible patients to the competition and risk missing approval and commercialization milestones. Sponsors also compromise patient access and diversity targets.

And let's not forget, more than 50% of investigators who have run one trial will never run another again due to the sheer complexity of clinical research. Modernizing and simplifying clinical trials enables sponsors to attract and retain investigators and the best sites to be the "sponsor of choice" for top investigators.

So, ask yourself, is your paper protocol making life better or worse for investigators?

The Problem for Sites

Time Poor Staff, Time Intensive Process

Is this person eligible?

How do I manage this toxicity?

What should I do at this visit?

For which trial?

Imagine what you'd see if you were a fly on the wall of a clinical site. Patients? Sure. The hustle and bustle of clinical staff rushing between consultations? Absolutely. Paper protocols gathering dust and PDF protocols in obscure offices separated from where patient visits are taking place? Most probably.

You'd also see how every clinical trial-based action begins with a question – and possibly, some head scratching. What do I do at this visit? Is this patient eligible for this trial? How do I manage toxicity? Should I dose modify? What concomitant medications are permitted again? Where and when do I ship samples? This isn't a criticism. There are a lot of pressures on sites today. Time constraints. Ineffective training. High staff turnover. Increased study complexity. Lack of real-time decision support from monitors and sponsors.

All of this means most site staff struggle to understand the intricate detail of the trial they're recruiting for. And getting hold of the answers is neither quick nor simple.

Sure, they're all contained within the clinical trial protocol... but where is that protocol? Most likely a paper copy is filed away and difficult for clinicians to access during patient visits or when off duty. Perhaps it's accessible as a PDF, via a web portal, but this requires clinicians to log into the portal in the first place and then hunt through hundreds of pages of complex data to find the answers they need. A 'Control-F' in a PDF yields dozens of hits scattered throughout the document.

Either way, obtaining quick and accurate answers that support timely and informed decision making – while the clock ticks and the queue of patients waiting to be seen grows – is a serious challenge.

As a clinician, if you end up attempting to overcome the problem by printing off your own laminated memory aids to speed up the process, you're in good company. Many resort to "cheat sheets" or similar, to have the answers to common queries quick to hand.

But, what if the protocol has been amended and the information is now out of date? What if by attempting to keep pace with the demands of the job, you're increasing the risk of protocol deviation and compromising patient safety?

Taking a "best guess" approach, especially when time is of the essence, is another favored solution for investigators. After all, adverse events don't respect office hours. When action is required urgently and investigators are off duty, is it realistic for them to stop what they're doing, drive to the site, physically dig out a paper protocol or locate the PDF, and search for the answer they need?

The Problem for Study Monitors

Compromising Risk Management and Competitive Edge

Increased protocol complexity

Version control

High staff turnover

Problems associated with paper and PDF protocols aren't limited to sponsors and sites. CROs (Contract Research Organizations) also bear the burden. Outsourcing to CROs remains a popular option for sponsors keen to run trials faster, improve efficiency and add specialized services – and it's only set to continue. As the scale and complexity of clinical trials increase, quality risk management is no longer a "nice to have" component of trial design and execution. ICH E6 R2 is the biggest change in clinical trial regulation in 20 years. It demands sponsors (and the CROs that operate on their behalf) adopt a more formal risk-based approach to clinical trial design and implementation, specifically when it comes to oversight and quality management. And herein lies the problem.

As more sponsors look to outsource, and as auditors expect higher standards of risk management from the CROs they outsource to, the resource intensive, reactive management of site adherence that paper and PDF protocols facilitate no longer cuts the mustard. Monitors are usually responsible for multiple sites and it's possible that each of their sites could be on a different version of the protocol. When study coordinators reach out via email to the CRA to confirm a procedure or clarify an ambiguous protocol reference, the CRA may be in transit, traveling to the next site visit. In this common scenario, the sites needing assistance are blocked. The CRAs become ineffective switchboards and sponsors find out too late what questions or issues sites are facing.

We know paper and PDF protocols make life harder for site staff, but CROs also struggle to get a handle on the risk of protocol deviations and violations. This is because – short of picking up the phone on an hourly basis or having boots on the ground at every site enrolled on the study – it's impossible to assess site engagement with the protocol in real-time. Not only does protocol complexity make it difficult to ensure sites are strictly adhering to the protocol and procedures, but monitors have the added challenge of keeping up to date on all active versions of the protocol and making sure sites only use the correct, approved version.

Paper and PDF protocols block monitors from seeing when site staff access the protocol and what they're searching for when they do. Sure, they'll see eventually when they visit, maybe six weeks later. Is that good enough to demonstrate a robust approach to risk management, especially when taking into consideration the high staff turnover of CRAs? And, compliance aside, if you're only able to identify potential issues with protocol adherence and implement corrective action retrospectively, is it cost-effective? In an increasingly competitive market, can you really afford for the answers to be no?

A Whole New World of Opportunity

Now, imagine a world where site staff have instant, current, relevant study answers anytime, anywhere from a digital device. Imagine how empowering research staff to receive immediate answers to their protocol questions could transform their working lives for the better and lead to faster recruitment and better handling of safety issues. Imagine how this could support them to assess eligibility and promote greater diversity, quickly and correctly. And in this new world, when patients pick up the phone in the middle of the night with an adverse reaction, imagine the relief felt by investigators, who no longer need to rely on a "best guess" because they have the information at their fingertips while they talk with the patient.

Imagine that monitors can be assured that only current, approved documents are in the hands of all site staff. And in this new world of opportunity, monitors have insights they need to better plan site visits so they can focus on sites that need the most attention. And CRAs maintain visibility into site questions that are directly routed to the best study experts, reducing time and frustration for everyone.

Now, imagine instead of it taking months to enroll the right quality and quantity of patients, enrollment is accelerated because clinicians can now identify eligible patients faster. And it's also easier for them to engage with your study over the competition. And then imagine how this could also support them to promote greater gender and ethnic diversity.

Congratulations! You're now the sponsor of choice.

What if, instead of sponsors and monitors being forced to operate retrospectively, they could spot issues that block sites sooner, improving efficiency and – more importantly – making participation safer for patients? And what if sponsors could also spot unexpected trends or aspects of the trial that sites need additional clarification on, or a need for information that is not in the current protocol?

What if they could achieve real-time visibility into site interaction with the protocol and therefore better understand patterns of engagement with it? What if sponsors could see which sites are searching the protocol as and when it happens? And what if sponsors no longer needed to wonder if their messages were being read by sites?

What if it were possible to assess site engagement based on the volume of searches and analyze those searches to proactively identify safety risks or the need for guidance? What if by doing all of this, we could reduce time to market for life-altering or life-saving drugs? Everybody involved in a clinical trial goes to work every day trying to do a great job. Working to be the best version of themselves that they can be. Ask yourself: are we supporting that by giving them paper protocols or portal PDFs? Is that the best we can do?

Have a Study Question? Teckro the Answer!

Every clinical trial starts with a question. So, let's make finding the answer quick and simple with a truly digital, mobile interconnected protocol. We know sites are overburdened with too much technology so this solution is one app for all protocols.

Digital

We've already embraced the benefit of digital access to information at our fingertips in all other aspects of our lives, so why not in clinical trials? When the protocol and other study content is truly digital with Teckro and not just an electronic version of paper, vital answers are instantly available, simultaneously to everyone who needs them – anytime, anyplace.

Much more powerful than a simple control-F in a PDF or blanket search in a portal, with Teckro study stakeholders now have an intelligent search engine for instant, accurate answers and prompts for suggested next best actions. Think of it as a virtual monitor that can help guide decisions and actions at each stage of the trial.

Better still, Teckro ensures that the right, currently approved version of the protocol for each site is available. Sponsors gain a level of oversight into site engagement with their study and visibility into the types of terms being searched. This new level of insight into trial performance helps sponsors and monitors to make data-driven decisions to better identify risk, proactively manage compliance, and engage in a more meaningful way with sites.

Mobile

Teckro is a simple, intuitive, familiar mobile app that connects all study stakeholders with study answers they need, when and wherever they need them. Downloadable from the app store, Teckro provides researchers with clinical trial guidance from the digital device in their pocket – something they always have with them.

Using native mobile functionality, site frustrations like remembering multiple passwords per study become a thing of the past - with Teckro, it's one app for all protocols. Push notifications direct attention to important study messages in an already familiar way.

Interconnected

Teckro is the one place to go for study answers – whether answers from the protocol itself or from study experts. Communication is centralized in the same app, so nothing gets lost in inboxes. Study experts cut down wait times for answers at the point of care. And CRAs don't need to be the person in the middle forwarding messages to study experts when sites have direct access to those with the knowledge.

Hurrah! The clinical trial protocol is no longer a static, physical document but transformed into real-time accessible, meaningful knowledge for research staff, monitors and sponsors.

What does this mean? The right patients are enrolled faster, protocol adherence improves, and safety issues are rapidly and effectively managed.

We're not describing an alternate universe. This world of opportunity is in the here and now. And it's one that many major pharmaceutical companies, emerging biotechs, and thousands of research sites already operate in, thanks to Teckro.

We manage the vast majority of our lives through our digital devices. So, why not clinical trials? It's time to address that elephant in the room and modernize and simplify clinical trials. It's time for Teckro.

Teckro digitally interconnects your study. One app for all resources and all stakeholders. Our unique design spotlights centralized collaboration as a key facet of operational efficiency. Take action through Teckro to implement a robust, impactful site relationship strategy - with effective, timely, targeted communication at its heart.

If you want to enhance your plan for effective outreach and get tips for improving the site experience on your study - we can help, reach out to our team to request guidance now.

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