ArcheMedX

5 Things Clinical Trial Sponsors Must Digitize Now to Emerge Stronger in 2021

Discover what you can do today to firmly **establish your competitive advantage** - to avoid being **relegated to the sidelines.**

Introduction

Will 2021 allow us to bid farewell to COVID-19? Whether we can eradicate this terrible virus or not, many of its impacts **will persist**.

To assist Sponsors and CROs in navigating this uncertain time, ArcheMedX recently released an industry report, COVID-19's Impact on Virtual Tech in Clinical Trials. It is jam-packed with data from clinical trial Sponsors and CROs that illuminates the path forward.

As we analyzed the findings, we discovered that clinical trial Sponsors are acutely focused on adoption of virtual activities across the clinical trial lifecycle and increasing trial readiness.

But this will not happen overnight, and many Sponsors struggle with where to start, especially as they confront on-going challenges during the pandemic.

Don't struggle. In this whitepaper we'll uncover five different areas where you can **begin today** to realize the benefits of virtualization in the short term**.**

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#1: Partner with teams, sites, and investigators that think digital-first.

Gone are the days that other industries can point to the life sciences and call us laggards. The speed with which we are transforming industry-wide is exhilarating.

Our survey results reveal this shift vividly. Trial leaders are rapidly adopting remote technologies and cutting through the inertia that often hinders such changes, as demonstrated by:

- 75% are **adopting technology that supports virtual activities everywhere possible**.
- 50% are converting all clinical operations meetings to virtual ones.

Since these trends are industry-wide, the pool of partners available that prioritize digital is deepening. **You can - and must - begin to expect your sites, investigators, and especially CROs to be digital-first organizations.**

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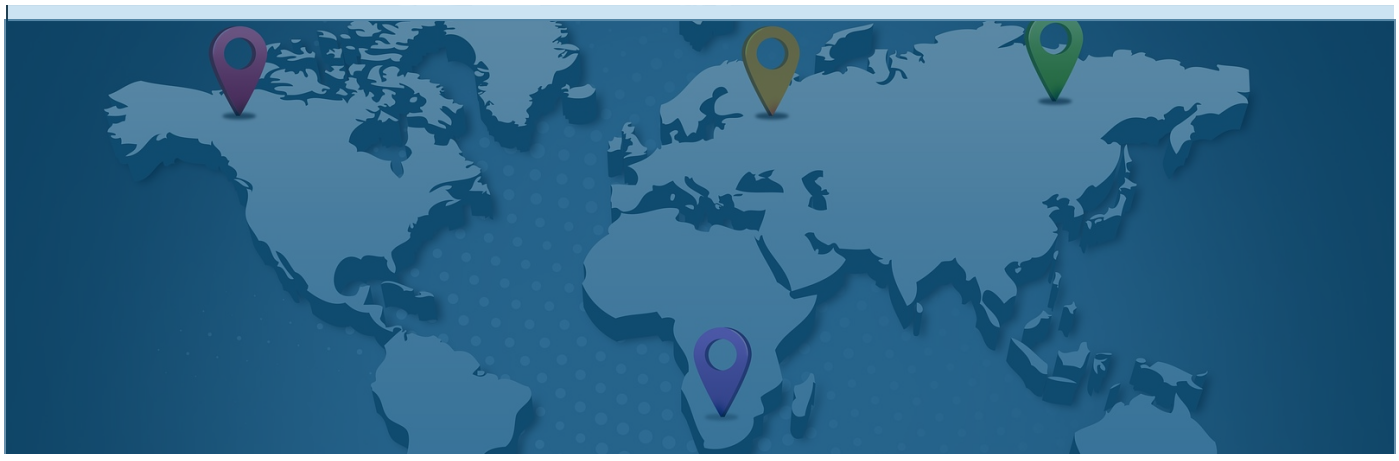
How you can select digital-first partners:

If this is your first foray into adopting virtual processes, you especially need to lean on partners that can help you ease the transition to a virtual future in your clinical trials.

Ask potential partners:

- What is your approach to virtual activities in the clinical trial start up stage?
- How much experience do you have virtualizing study start-up?
- What technologies are you using to support virtual clinical trial activities - especially with training the project team, and performing site selection, PI meetings, and site initiation visits?
- How are you leveraging data to better inform operational decisions?
- What is your digital and data analytics plan for the next 12-24 months?
- How can you help us be more effective with digital technology?

Digital-first CROs, in particular, should have clear and specific answers to these questions. Even if you're not ready to switch partners, begin asking these questions to understand how capable your partners are today, and where they are planning to invest.



#2: Site selection is an **immediate digital opportunity**.

In our survey, 77% of trial sponsors and CROs said they want to improve how they identify which sites are ready to start a trial by virtualizing site selection. **Your competition is digitizing this process - so you need to as well.**

COVID has made site selection more difficult by limiting site feasibility visits and the time sites can spend responding to Sponsors early in the process.

But **speed and accuracy are the greatest benefits** of digital transformation in site selection. Though today's average time to form a site list is around 2-3 months, by eliminating travel and using predictive insights from a digital platform like Ready, you can identify the rights sites faster.

How to digitally transform site selection:

Virtualize core procedures to reduce your workload. Enabling staff to complete selection tasks digitally allows you to deliver study information and collect site intelligence more efficiently. It also provides the ability to analyze more impactful data, **greatly increasing your likelihood of activating capable sites**.

Leverage the virtual PI meeting to inform selection. Sponsors using Ready can transform the PI meeting and also assess investigators and sites on their understanding of the protocol, eligibility criteria, familiarity with the patient population, and other key indicators. This paints a truly accurate picture of whether a site is ready to enroll.

Use confidence-based assessment to determine whether site personnel are prepared to conduct the study. You spend so much time preparing the content for your studies, but how effectively do you measure whether sites are ready to implement it? Adopting confidence as a metric enables you to pinpoint what participants understand, and what they can confidently apply during the study. **This allows you to be far more discerning in selecting your sites.**

Adopt digital tools to certify that sites can use the electronic equipment and systems required for your study. This is the simplest area to virtualize of all: validating preparedness to use critical electronic systems and other equipment.

Adopting digital methods for site selection will accelerate and improve your ability to choose the sites most likely to perform in your trial.

#3: Reimagine the investigator meeting for any new trials.

Before the COVID-19 pandemic hit, the live, in-person principal investigator (PI) meeting was a non-debatable necessity in any clinical trial. Unfortunately, it also made up a hefty budget line item - with the average price tag coming in close to $1 M USD for a global series of PI meetings.

COVID-19's restrictions have forced Sponsors to adapt. 67% of our respondents to the survey felt PI meetings should be in-person before COVID-19. And nearly half had **never used on-demand virtual meetings** to deliver a PI meeting.

How times have changed. Spurred by COVID-19, the industry has embraced the shift to the virtual investigator meeting. **65% of Sponsors** now believe that a virtual meeting can be just as -- or even more -- effective as a face-to-face one.

How you can implement a virtual PI meeting:

Pre-COVID, virtual technology use for investigator meetings was extremely low. Thus, the 60% of Sponsor respondents to our survey that are planning to replace in-person meetings is an enormous change that will require planning.

If you're preparing to make this a capability in your organization, don't just shift your baseline PI meeting approach to a web meeting.

To really succeed with a virtual meeting, you must transform the meeting agenda and delivery. You'll be more effective in achieving the ultimate goal: preparing PI, study coordinator, and CRA attendees to succeed in your clinical trials.

First, get the right technology for your investigator meeting. Ideally, you will use a solution that can service most if not all of these virtual activities, and not just the PI meeting. This lets you spread the cost across activities, and maximize the adoption of your digital-first mindset.

With the right tech in place, plan (then deliver) a virtual-first meeting agenda. The tips we suggested for virtual training are great for use here, too.

Make sure that you plan how you will measure outcomes from the meeting to help you asses their readiness to actually conduct the study. Take advantage of the virtual nature of the meeting to capture additional data that can inform your study start up - and ultimately demonstrate the efficacy of the virtual version of the meeting.

Need more details? Get the rundown in our blog "Running a Virtual Investigator Meeting in 4 Steps."

#4: If you haven't gone fully virtual with training, **now is the time**.

When was the last time you conducted a face-to-face training for -- well -- anyone?

Our survey revealed that training was already the most digitally "mature" area of the clinical trial start-up. **A majority of 65% of life sciences leaders reported using virtual delivery at least some of the time**.

And specifically speaking, site training was the most digitally advanced in a broad sense.

Now, with more than half of Sponsors endeavoring to fully replace in-person activities with virtual, **do not be left behind.** Your partners - notably CROs - will also expect you to shift to a virtual training model. If you haven't made the change, you need to - and it's an easy and quick win.

How to make the shift to virtual training:

Virtual training is not a check-the-box exercise that simply replaces live training. It is a much more efficient process and data-rich opportunity. Virtual training allows your teams to participate more easily and enables you to measure results and ensure your investigators and sites are fully prepared to conduct the study.

To make the jump, there is some planning that you must do, but it is straightforward. These planning steps are:

Establish the objectives for your training - in order to measure them. What learning objectives do you need to achieve?

Verify that your training content transitions to a digital experience well. If your existing training content isn't engaging enough, you're much more likely to lose the site staff audience in a virtual setting. Want to achieve success? Check out these tips to ensure you deliver a premium virtual training experience - and prove the effectiveness afterwards.

Select a learning experience platform, like Ready, that can deliver your training effectively and help you measure how prepared your teams and site staff are to conduct the study. Need help making sure you choose the right tool? Here's a checklist that will help you.

Fortunately, most of your team members and staff should be very amenable to taking online training. Because of the pervasiveness of online learning today, with the right platform you can spend more of your time planning how to leverage your training data, and less on managing content and users.

#5: Virtualize Site Initiation Visits to reduce your workload.

You already know there is a lot of work to activate each site so they can start enrolling. And creating a virtual process to do this will help you in both the short-term and future studies.

Site initiation is yet another area that your competitors are focusing on: across our recent survey, **84% plan to increase their use of virtual delivery of training during site initiation**. 50% overall plan to replace in-person meetings wherever possible for the SIV.

The benefits are broad if you undertake such an effort:

- Create efficiency and scale (reduce travel, optimize staff assignments).
- Reduce the work necessary to develop and deliver the training.
- Ensure consistency in what site staff are learning and evaluate their actual preparedness.
- Quickly identify risks in specific sites and staff ahead of activating the site to enroll.
- Enable trial leaders to focus on the most critical study objectives for each site.
- Complete visits faster – so that sites can begin enrolling patients sooner.

How you can adopt the virtual SIV:

You can virtualize nearly all of the SIV: documentation, site staff training, and much of the site initiation visit itself. There are numerous tools to help you acquire necessary documentation and contract agreements from the sites, for example, which reduces time a great deal.

If you're planning to take your PI meetings virtual, you can and should use the same technology you adopt there for virtualizing the site initiation visit. Then, you can use many of the techniques we've shared for preparing your content for virtual training to develop your curricula for sites.

Clearly, the great benefit of a virtual SIV is the richness of the data and the ability to objectively measure site readiness - something that has been a subjective process for too long. With more insightful data, you can reveal areas where your sites need additional preparation, so you can focus your time and resources only on the sites that need more help, and the topics that need more clarification.

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The steps you take toward virtualization today will define your success in the long term.

It remains to be seen how quickly digital change will result in true transformation for our industry. But we know that the steps we take now can pave the way for trials that are less expensive, more accurate, more accessible, and more timely. And these five areas are realistic moves that you can make - now.

Clinical trial Sponsors have been clear that they are adopting virtual technology and processes to overhaul the vestigial study start up. So the question is - will your organization make the digital jump - successfully?

Ready by ArcheMedX can help you navigate the transition to a digital-first clinical operations model. So don't struggle. Let us help you get started on your path to virtualization today.