

September 2023

# Prioritizing Agility When Choosing a Contract Research Organization (CRO)

Author: Josée Comeau

The  
**VANTAGE**  
Point

### Introduction

Throughout the years, the field of clinical research has continued to grow in complexity and has encountered numerous challenges, and although processes have been well established, many of us have settled into a daily routine that maintains the status quo.

It's time for us to move away from traditional practices and introduce a concept that some niche CROs, like Vantage BioTrials, have been utilizing effectively since the early days of the Covid-19 pandemic, namely using agile methodologies in running clinical trials.

### Perspective

As per ClinicalTrials.gov, there is well over 64,000 recruiting studies that are “ongoing” in status. We started 2023 with approximately 437 000 registered studies as opposed to 137 000 in 2013 (which equates to a ~320% increase over a decade).<sup>1</sup> Have our resources grown to cover those needs? Not even close. As our workforce has been shaken by a pandemic, high turnover, new regulations and restrictive budgets for the past few years, resourcing and manpower challenges have exponentially grown as well.

To compensate, some have attempted to re-structure themselves and found more efficient ways to work but, in the last few years, for many of us, it hasn't seemed enough to keep our head's above water for the long haul. As we strive to achieve excellence in managing clinical trials, we need something more to accelerate our progress and conduct these studies in what we would sometimes refer to as a “smoother process” and gain efficiencies. It has become essential to bring in more experts who understand the intricacies of research and enhance process flows with agile frameworks.

### Agility is Key

When it comes to effectively managing clinical trials, an agile methodology has become increasingly important in light of the challenges posed by high turnovers and low staffing. Bounded by communication breakdowns, delays in timelines, and other deviations that can negatively change the outcome of a clinical study, it's clear that we need to find new and innovative ways to work more efficiently as we settle into a reality that brings forward long-term impacts. With the flexibility of an agile framework, we can adjust our goals and objectives in real time and keep up with the constantly evolving environment. This agility also means that we can make quick decisions based on available data and adjust our strategies accordingly. A solid risk-management plan should be prepared by the study team well in advance of the “first patient in” milestone, and continuously verified, analyzed, maintained and updated as the study progresses.

1 <https://clinicaltrials.gov/ct2/resources/trends>



## Prioritizing Agility When Choosing a CRO



Agile management is all about being adaptable and flexible in your approach, and it can be especially useful in the context of managing and monitoring of clinical trials. As the pioneering software engineer, Barry Boehm once said, “Agile methods derive much of their agility by relying on the tacit knowledge embodied in the team, rather than writing down their knowledge in plans.” It also helps to break down large projects into smaller, more manageable tasks, so that teams can easily adjust to changes and challenges as they arise. An agile approach

helps keep timelines on track and ensures that everyone remains focused on the study’s ultimate goals.

### Be Empathic

Let us also switch gears for a moment and look at the current situation through the lens of clinical trial sites; in general, many sites have had to tighten their belts and over-stretch their resources in order to keep up with the demand of the sheer volume of trials being thrown at them from Sponsors, and this has led to many sites refusing to work with certain types of Sponsors or CROs, creating a further gap between the number of available sites to perform the required studies. Down the road, this can lead to entire clinical programs being cancelled due to lack of qualified sites required to perform them. To combat this negative trend, as an example, Vantage BioTrials has embedded a culture of cooperation and collaboration between our staff and the sites we manage, acting as ambassadors (not adversaries) when performing site management activities on behalf of our Sponsors. Part of that success stems from effective communication strategies between all stakeholders that results in leading through empathy in order to understand the needs of our sites and supporting them with additional training, occasional check-ins, and a supportive hand when required.

### Think Outside the Box

A major lesson that the Covid-19 pandemic taught us is that with workforce shortages, sometimes we also must settle for who is available; this can create diluted knowledge but does not necessarily translate into failure. Vantage BioTrials’ experienced team can support your study by adapting to its needs with agility, analysing requirements for technology and automation, quickly adapting in order to streamline operations and ensure tasks are completed efficiently and effectively. It can lead to more accurate and consistent results and tremendous success for your projects.



## Prioritizing Agility When Choosing a CRO

Another significant challenge facing the scientific community is the environments in which we work, and the communication strategies we use.

Scientific research plays an enormous role in our daily lives, and we were lucky enough to see the power of teamwork pull together worldwide as we survived through the global pandemic. In that sense, the entire world was forced to become “agile” very quickly. It allowed us to prioritize our well-being with an adaptive and flexible work environment, but also keenly bringing to the surface other challenges already present.

Although the status of the “pandemic” officially ended a while ago, one of the most significant impacts it had on science is the way it forced us to reconsider our work environments. With so many people working remotely or taking time off due to illness, it has been challenging to keep science moving forward at its usual pace. As a result, many studies now face delayed timelines, and research data is being affected. As it is challenging to plan and prevent these issues, it is also crucial we move forward swiftly for the sake of scientific progress.

Even if remote working can bring many positive outcomes for productivity, the disruption in communications and the isolation from not being in the office are significant. Perhaps most concerning of all is the impact that mental health challenges are having on advancing research projects. The McKinsey & Company survey mentioned that more than half of Americans between the ages of 18 to 34 struggle with mental health issues, affecting their work performance when working from home. Distractions, isolation, and a lack of contact with colleagues can all contribute negatively, which is where strong communication



strategies come into play.<sup>2</sup> Teams spread out across different locations or working remotely need to stay in touch and communicate effectively using tools like video conferencing, instant messaging, and other collaboration tools. By maintaining open lines of communication, teams can work together more effectively and ensure the research progresses smoothly. Maintaining proper communication can also be especially challenging for new employees who have yet to have the chance to build relationships with their coworkers and get a sense of the company culture. For them, it translates into less peer recognition and less acknowledgment of the company’s values. Their roles are often unclear due to the nature of the communications, and the distractions from home can be difficult to overcome and impacts productivity.

<sup>2</sup> <https://www.mckinsey.com/industries/real-estate/our-insights/americans-are-embracing-flexible-work-and-they-want-more-of-it>



## Final Thoughts

Keeping a team motivated and on track can be challenging, let alone transferring knowledge and work competencies with a lack of fluidity between internal groups. Clear communication is vital for the success of any scientific or business venture, and the pandemic put that to the test. It is crucial to also prioritize flexibility and agility when planning clinical trials. This means being open to changes in our approach and being willing to adapt as necessary to ensure the research stays on track. This is when risk-based management and monitoring becomes crucial as a skill and as a tool. By being prepared for unexpected events and ready to shift gears when necessary, teams can better manage the trials and ensure that they successfully reach their goals. By prioritizing open communication, breaking down larger projects into manageable tasks, and staying adaptable in the face of challenges, teams can navigate the complex world of clinical trials and ultimately achieve success.

Moreover, partnering with a strategic niche CRO like Vantage BioTrials can be a game-changer when meeting goals and objectives. Experienced CROs bring a wealth of knowledge, resources, and expertise to the table, which can help to fill any skill gaps within the team. A niche CRO can also provide valuable insights into potential roadblocks or issues that may arise, allowing sites to plan proactively and avoid any possible delays or failures.

The pandemic has shown us how capable we are of adapting to new circumstances and coming together as a team to solve problems. We must continue to prioritize clear communication, efficient workflows, and a solid commitment to our shared mission of advancing knowledge and improving people's lives. Only then will we overcome these challenges and emerge stronger on the other side!

---

## About Vantage BioTrials

Vantage BioTrials is a leading Canadian Contract Research Organization (CRO) with a proven track record of successfully completing & delivering clinical trial milestones on time and on budget. Since our inception in 2007, we have used innovative clinical trial management strategies for the life science industry with a focus on patient safety & advancing new therapies to market. We offer pharmaceutical, biotech & medical device companies a complete and integrated set of full-service clinical trial management solutions, based on the principles of Quality by Design and Risk-based clinical trial management.

Contact us today at [info@vantagebiotrials.com](mailto:info@vantagebiotrials.com) and discover how we can add value to your next clinical trial program.