Putting patients at the centre of clinical trials

A guide for clinical research organisations

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A focus on the patient experience

Discovery accelerated: Navigating the world of decentralised trials

While decentralisation of trials was born out of necessity when COVID-19 made its way into the world, it also offered CROs the opportunity to reevaluate their existing processes and as a result both improve the patient experience and cost margins.

Not too long ago, the idea of decentralised clinical trials and virtual visits was just that — an idea. Between 2018 to 2020, the number of companies using decentralised methods for clinical trials doubled. Now in the post-pandemic world, decentralised trials are a norm, but the best practices surrounding them are not.

To understand the extent of this impact — and how CROs can best chart a path toward making this newer format a success — Certinia convened a panel of experts to discuss the topic and to share recommendations:

- Christof Wascher, Senior Director, Industry Advisor Life Sciences, Salesforce
- Kimberly Tableman, Chief Clinical Development Officer, Castor
- Ben Adams, Senior Editor, FierceCRO and FierceBiotech
- Andy Campbell, Product Evangelist, Certinia

This ebook presents highlights of the discussion and some of the insights, opportunities, and foundational elements CROs can call upon to achieve the ultimate integrated patient experience.

“It wasn’t that long ago we referred to patients as ‘subjects’ in the clinical research experience. Now we call them patients and people. We’re moving along the continuum and now need to focus on the patient experience.”

Kimberly Tableman
Chief Clinical Development Officer, Castor

Ushering in the integrated patient experience

The cost and timeline to develop a new drug can be cut down dramatically by making patients more central to clinical trials and conducting better trial matchmaking services.

Today, it's complex and labourious for patients to find the best trials for them. They need to scroll through websites in their countries to try to find a match. At the same time, the CRO industry spends billions of dollars over many years developing a drug.

It's up to the industry to find and offer a centralised approach that uses available technologies while keeping the patient at the heart of trials. For instance, they can call upon a number of ways to reduce the number of patients needed for clinical trials (such as by using digital twin data). A customer-centric approach will elevate the patient experience while also helping reduce trial costs and time to market for new drugs.

One area for capturing the greatest impact and cost savings as relates to running a clinical trial using decentralised methods is what Castor — a leading provider of clinical trial technology — calls enabling an 'integrated patient experience.' This covers everything from how people find a clinical trial, pre-screen, enroll and consent — all virtually.

This innovative technology vendor isn't just imagining a future scenario. It has seen this happen.

Castor partnered with the World Health Organisation on a study called COVID Red to run clinical trials related to the COVID vaccine. The company recruited and enrolled 17,000 patients in 15 weeks on its platform — a process that typically would have taken two or more years in the past.

Similar examples abound. Johnson & Johnson ran a single shot COVID vaccine through its CRO almost completely virtually. "It called upon a mix of these telehealth technologies, virtual oversight and digital patient engagement strategies to run one of the most visual vaccines we've ever seen," underscores Ben Adams, Senior Editor for Fierce.

From a technology perspective, it's possible to enable a seamless patient experience when it comes to educating people on clinical research and allowing them to pre-screen and enroll — all from home.

It's clear the entire Health and Life Sciences industry must support the patient desire for simple procedures such as getting a blood pressure reading, whether through a primary care physician or a local pharmacy.

While everyone wants trials to be accurate, time is needed in the clinic and during regulatory review. Many CROs have got through this quickly because hurdles around paperwork and waiting for clearance were readdressed and overcome with the push to accelerate COVID vaccines.

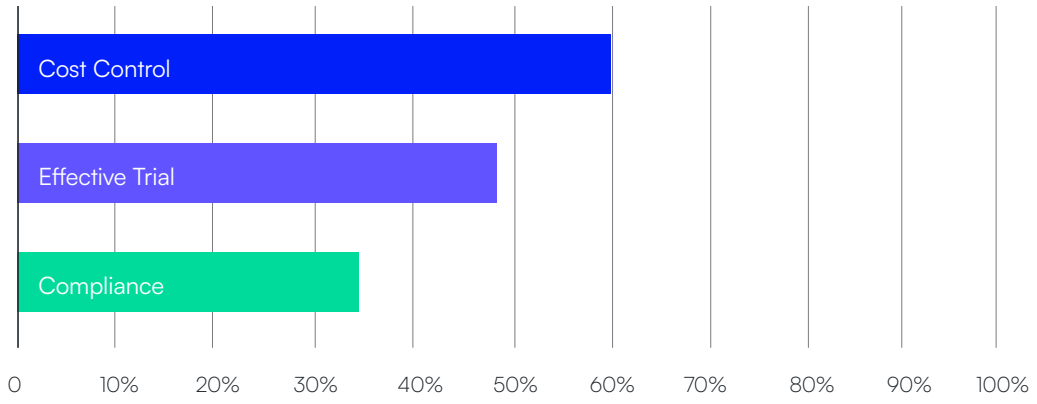
“If we can do more to streamline the regulatory process, we’ll see drugs go from bench to bedside much more swiftly.”

Ben Adams
Senior Editor, Fierce

Adams also emphasizes that this opportunity is available — and of great interest — to CROs that aren't working on infectious disease or vaccines but instead are working on cures and medicines for heart disease, cancer and COPD, to name a few. The opportunity to more quickly and effectively develop drugs promises better outcomes for both CROs and patients.

However, to realize that vision, the industry must find ways to address entrenched challenges. As shown below, a recent Fierce Life Sciences survey on The Future of Clinical Services found the biggest challenge around clinical trials is cost control, followed by effective management of trials.

What are the key challenges that you – as a CRO – currently face?

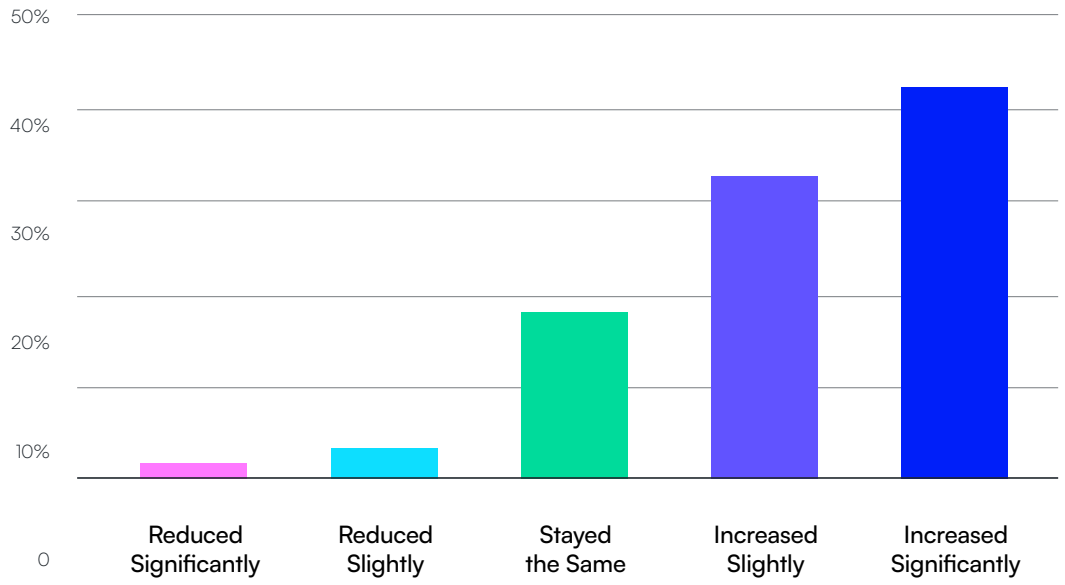


Paving the way for ecosystem healthcare

CROs can overcome these hurdles and reduce friction in the clinical trial process for patients — and the general patient experience — by leveraging digital ways to interact and engage. Fortunately, over 75% of organisations surveyed by Fierce Life Sciences intend to invest more in digital transformation initiatives (see below).

One technology vendor enabling the ecosystem to be more cost effective while elevating the patient experience is Salesforce. It calls the use of digital means to interact and engage "hybrid engagement."

Please fill in the blank: "Emerging from the pandemic, your plans for digital transformation have _____."



“Life sciences companies will be able to differentiate themselves in the market by embracing a personalised, integrated care approach, using technology advancements to put patients in the centre of the ecosystem.”

Christof Wascher
Senior Director, Industry Advisor Life Sciences, Salesforce

It's just this type of model that will enable what consumers are increasingly demanding: personalised therapies. "Targeted individual treatment approaches need to be orchestrated with the patient at the centre of a mini network," says Adams.

In fact, Christof Wascher, Sr. Director, Industry Advisor, Health & Life Sciences, posits that hybrid engagement will change the industry. As an example, he points to Estonia's Connected Health ecosystem, saying it puts Estonia 10 or 12 years ahead of the rest of Europe.

Currently, this ecosystem comprises 50+ partners, including 30 companies (start-ups, health IT, medtech, biotech, and pharma), R&D partners (universities and technology competence centres), health and care service providers (hospitals, GPs, occupational health), and patient organisations and user communities. It also includes public sector organisations, including ministries responsible for healthcare and entrepreneurship, Health Insurance Fund, and the National Institute for Health Development.

In the Estonian ecosystem, payers, providers, pharma, and MedTech leverage an established data standard to exchange data and enable efficient healthcare interoperability resources.

"This is the future and a great role model for how the ecosystem could evolve with the patient in the centre," says Wascher.

In fact, CROs and pharmas can take advantage of partnership opportunities with digital therapeutic-type companies and the ecosystem at large. Many companies are doing innovative things from a technology perspective and pushing the envelope when it comes to enabling flexibility and choice in clinical research. "At the end of the day, the winners are the patients who have a better, enhanced experience and are more engaged overall with clinical research," adds Kimberly Tableman, Chief Clinical Development Officer for Castor.

“Enabling patient convenience requires flexibility and a patient-centric mindset with a renewed focus on patient and clinical outcomes.”

Andy Campbell
Product Evangelist, Certinia

Data becomes the new currency — but processes lag

While many organisations are well on their way to leveraging the requisite digital technologies, just as many still struggle when it comes to data. Reducing friction in the clinical trial process and the general patient experience also hinges on seamless data integration and exchange. Simply put, in both clinical research and general healthcare, data is the new currency. The key is data collection and the ability to prove safety and efficacy of a therapy while enabling patient convenience. At every stage, patients deserve a complete record of their procedures.

It's not data integration that is difficult. The biggest challenges are filling in data holes and standardising data collection. What's essential is being able to ingest data from various sources in a standardised, usable format that makes it possible to derive meaningful insights.

Organisations may start with data specific to a clinical trial record and then try to layer in real-world data, such as from an actograph, sleep study, or genetic information. With a lot of noise in real-world data, it's critical to understand what is important in that data and only pull out meaningful signals. It's impossible to train machine learning without understanding the data and being able to pull insights from it.

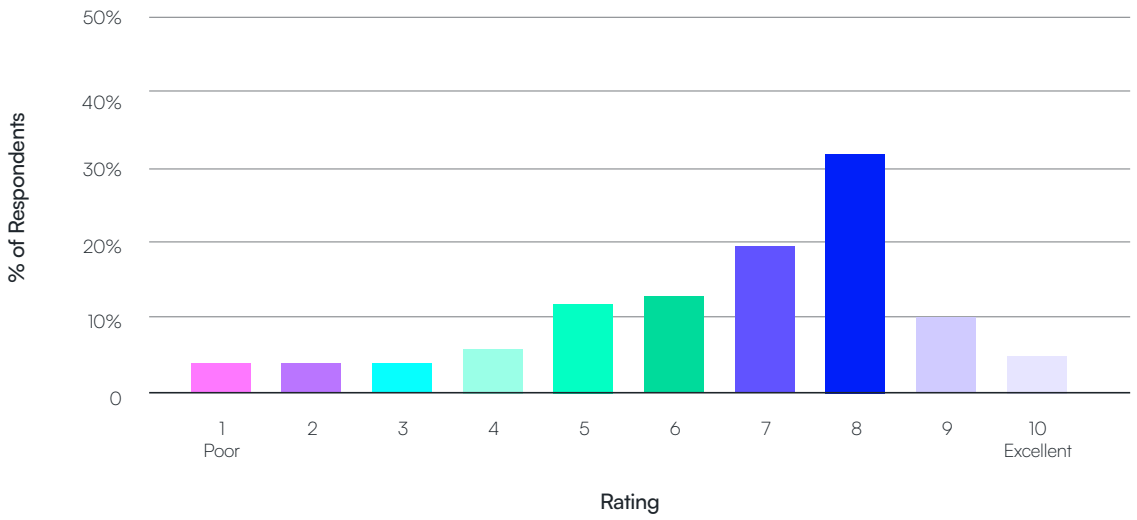
As Adams says, "We talk a lot about artificial intelligence (AI) and machine learning but need to get the basics right. The health record is not a consistent centralised process and even with new technologies and new platforms — like AI systems and algorithms — you've still got the 'swivel chair interface' where you must manually input data."

Data also needs to be captured from an end-point perspective, and some issues for CROs are related to the number of endpoints being captured. This is partly due to the legacy and the history of how CROs have managed clinical research. Each study is treated as its own independent entity. "There is a push in the industry to focus on the data needed to generate a study hypothesis, rather than going far down the line with secondary and tertiary endpoints," says Tableman.

When doubling down on drug development, CROs need the right data fast to make the right decision. A great data architecture is a must. But companies need to connect all the data coming from different areas, such as early research. It's about improving process data flows to enable better and more data-driven decisions.

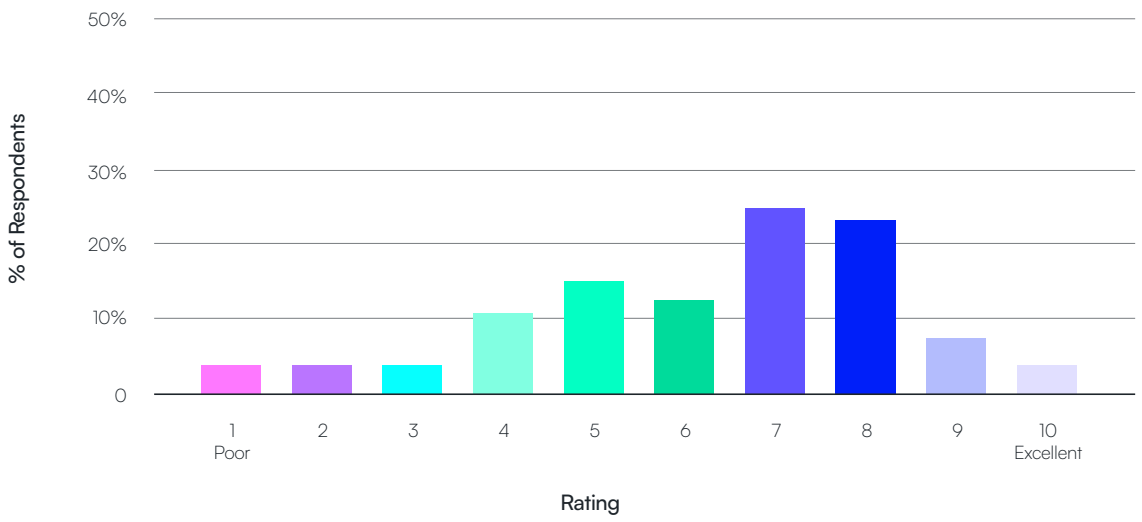
In line with this, Fierce Life Sciences' survey found that just 40% of organisations rate the consistency, timeliness and quality of their data for use across the enterprise as good or very good (see below).

On a scale of 1–10, how would you rate the consistency, timeliness, and quality of data (pre-clinical, clinical) across your enterprise?



More significantly however, only about 20% of organisations felt that their processes for delivering clinical services effectively were tightly integrated enough (see below). This is an important disconnect to address since these processes deliver the data that CROs base their decisions upon.

On a scale of 1–10 (where 1 is poorly integrated and 10 is highly integrated), how seamless are your clinical service planning and delivery processes?



These disjointed processes increase costs and the potential for mistakes, omissions and duplications, and lengthen the drug development time frame. Moreover, they exacerbate the issues related to multiple sources of data. Namely, CROs are at risk of the 'swivel chair interface' issues that lead to higher errors. It's not enough to put data specialists in place. If underlying systems aren't well integrated and data-generation processes are not optimal, data specialists are at a disadvantage with the data available to them.

While such problems are common when processes span departments, they are compounded when CROs work with third parties across the complex drug development value chain. Simply put, process issues become more problematic as they proliferate throughout the value chain. To ensure the best outcomes, CROs must ensure the most efficient processes internally and across their partner network.

With that in mind, Salesforce has doubled down on enabling data integration. Salesforce can virtualise data out of a given data lake while addressing the need for data residency and data compliance. From there, it is possible for people to leverage relevant data using the software's engagement capabilities.

Ready accessibility to trial data can serve another purpose. As Adams says, CROs need to release trial data as swiftly as possible for the scientific community. "Whether the data is negative or the trial didn't hit the commercial heights the sponsor had hoped for, it's not okay to bury the results. At the very least, participants and patients deserve to be honoured for what they've done for their trials."

“Once we’re able to glean insights from data and drive those back into study design earlier in the clinical research process, we can call upon machine learning and artificial intelligence to launch smart trials, which is game-changing.”

Kimberly Tableman
Chief Clinical Development Officer
Castor

Ensuring accessibility and diversity

In the midst of all these industry changes, it's important not to lose sight of the issue of accessibility and diversity.

Adams underscores the lack of diversity in gender and race in trials. "African-American or race identified as Black accounts for 13.4% of the US population, but the trials used to approve new medications for COVID vaccines only included 3% African-American or Black." It's a similar story when it comes to other races, such as people of Asian and Hispanic descent.

Decentralised trial methods can help here too by making clinical trials more accessible to more people. These methods also provide an opportunity for the industry to build relationships within communities to increase trust. During the pandemic the global population became aware of their COVID vaccine maker, and felt strongly about the brands — something unheard of in the past.

Moreover, recruitment and retention could be helped with a more open community where potential patients could learn about drugs, CRO philosophies and where patients fit within that.

Wascher encourages CROs to see what's possible within the given legal frameworks with regard to creating these patient communities. "With today's technology, it's possible to create these communities and practice-sharing groups. That's why it's important to come up with a strategic data integration motion for uniting data assets. Rather than take a point-to-point solution approach, take a more strategic, integrated approach to support the larger vision."

Conclusion:
Keep patients at the centre

Virtual, democratised, and distributed trials are here, driving more urgency around not just capturing patient and trial data, but capturing the right data. Success starts with embracing a patient-centric mindset and taking advantage of proven technology and processes — as well as new partnership opportunities — to expand the current trial approach. By doing so, CROs can address awareness, diversity and inclusion, and outcomes to ensure a next-level patient experience.

That said, without a personal motivation, people are not going to participate in trials. As Tableman concludes, “I would love to see clinical research reach a place where people feel they are well taken care of in the context of their participation in a clinical trial.”

So what are you waiting for?

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