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European Industry Research Report: The Future of Clinical Trials

How the pandemic propelled clinical research into the 21st century

Table of Contents

Foreword	3
Introduction	4
The impact of the pandemic on clinical trials	5
The power of technology	7
The increased focus on patient centricity	11
Summary	14
Methodology and demographics	15

Foreword

The pandemic has been challenging for us all, whether on a personal level or in a professional capacity. Although we have lived with the virus for over two years, it has had and continues to have a massive impact on our lives. As the pandemic struck, the pharmaceutical industry sprung to action, demonstrating resilience, a strong spirit of collaboration, and the will to adopt technology more widely in the face of adversity. This spirit of cooperation is something we need to continue.

When I first started in the healthcare industry, the internet had barely kicked off. Now, technologies such as decentralized clinical trials, wearables, sensors, electronic consent and electronic patient diaries are changing the way the industry approaches clinical development. While some of these solutions have been around for some time, the pandemic forced us to truly adopt them to ensure that clinical research could continue. The application of these technologies has allowed us to become more patient-focused and to run clinical trials with the patient at the core – engaging them in every step of the process from protocol design to follow-up after trial completion. It's essential that we prioritize patients in the clinical trial process, as without them we would be unable to bring new life-saving drugs to the people who so desperately need them. Fundamentally, the technology which we have begun to adopt more widely has shifted both industry and patients' mindsets.

While this progress is a fantastic development, it is crucial that the industry continues to collaborate and work with regulators to involve patients even more. This change won't happen overnight, but I am hopeful about the future of the industry, especially having heard from 400 industry executives in this report who share this vision. As the respondents in this report highlight, communication between regulators, companies and patients will need to continue to improve to enable us to evolve and prioritize those at the center of the process: patients.

I am proud of the industry's achievements over the past few years and the direction in which we are going. At Medidata, a Dassault Systèmes company, we have seen real change in the way clinical trials are approached and we are excited to see even more innovation and progress. It's been great to hear from key industry executives on what they view to be the key issues impacting the industry and some of the barriers in the clinical trial process. As you will read in the following pages, the industry is implementing its learnings from the pandemic and is embracing technology for the benefit of patients. The future of clinical trials and drug development looks bright.

Pete Buckman,
EMEA Site Leader and
SVP of Professional
Services at Medidata

Introduction

All new medicines - from painkillers and antibiotics to cancer treatments, vaccines and Alzheimer's drugs - have one thing in common: they must go through rigorous clinical trials before they are approved and made available to the public. Without patients, these trials would not be possible. Patients are the cornerstone of every clinical trial and their willingness to take part - and to follow through to the end - is paramount.

The healthcare industry has made good progress over the last few decades in addressing patient needs, making clinical trials more efficient and putting patients at the center of clinical research. But the sector and its regulators are, understandably, conservative and change has tended to be tentative and cautious due the fact that peoples' lives are involved. Then the pandemic struck, the world was plunged into lockdown and everything changed. Pharmaceutical companies and clinical research teams were faced with the prospect of shutting down trials altogether.[1] Life-saving drugs that were perhaps months away from approval might not hit the market for years.

The response was astonishing: the industry adapted quickly by adopting new technologies and modernizing trial designs to allow them to carry on.[2] Regulators, in turn, responded positively by accepting this new way of working and changing their regulatory frameworks[3] (which might otherwise have evolved over decades). It meant clinical trials became more patient-centric, allowing patients to spend more time at home and less time in the clinic; it meant crucial real-world data was collected en masse; and it improved enrollment adherence. This, combined, has resulted in more efficient and more diverse trials and, in turn, yielded stronger data and better outcomes.[4]

This report looks at how clinical trials have changed and are continuing to evolve. It details insights from 400 clinical trial executives across the United Kingdom, France, Germany and Switzerland who took part in a survey conducted by Vanson Bourne and sponsored by Medidata.

Key takeaways include:

- **Clinical trial processes will never be the same.** Organizations had to adapt quickly to continue their operations as the pandemic spread. These changes have improved clinical trials.
- **Demand for decentralized solutions continues to rise.** Decentralization and patient-centric practices have been core elements of change and organizations anticipate these solutions will become increasingly widespread.
- **Clinical trials will become more reliant on technological solutions.** From big data and growing computer power to wearable technology and artificial intelligence, organizations are adopting new innovative tools and solutions - and they are here to stay.
- **Patient centricity continues to be a key focus.** Patients are central to clinical research and there is greater recognition that trials need to be designed around them.

References:

1 - https://www.nihr.ac.uk/news/dhsc-issues-guidance-on-the-impact-of-covid-19-on-research-funded-or-supported-by-nihr/24469

2 - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8617428/

3 - https://www.gov.uk/guidance/guidance-on-minimising-disruptions-to-the-conduct-and-integrity-of-clinical-trials-of-medicines-during-covid-19

4 - https://www.nature.com/articles/s41746-021-00473-w

The impact of the pandemic on clinical trials

Emerging stronger: Learning from challenges brought by the pandemic

Almost all (99%) respondents say that the pandemic negatively impacted their ability to conduct trials. Only a small proportion of the surveyed participants (6%) felt that their organizations faced minor or no impact. Throughout the pandemic, organizations struggled to operate normally.[5] Lockdowns, threat of contagion and overwhelmed healthcare providers put a strain on clinical trial operations - patients were unable to get to clinics and resources were stretched as the industry focused on vaccines and treatments for the virus. This forced companies to review their clinical trial processes and switch to remote or virtual trials, adopt wearable technology and other innovations to continue the conduct of clinical research and the development of new drugs and treatments.

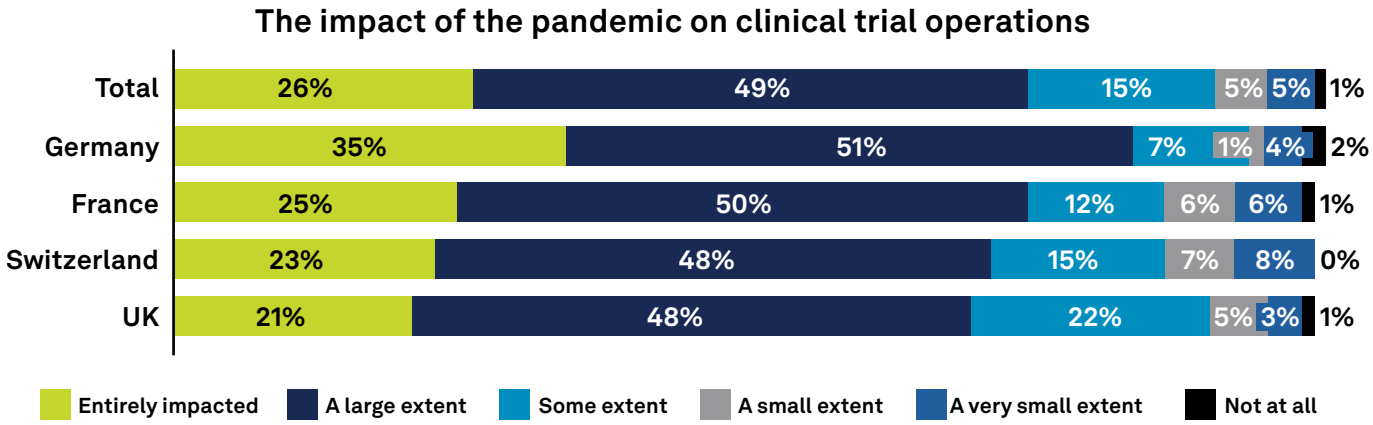


Figure 1: To what extent were your organization's, or your customers' clinical trial operations negatively impacted by the pandemic? [400], split by country, omitting some answer options

Most of those surveyed (98%) see improvements in their clinical trial processes due to the pandemic. While 35% of German respondents were likely to be entirely impacted, they also report the greatest improvement to clinical trial processes, with more than two-thirds (68%) citing significant progress.

Similarly, 85% of respondents across the regions who say their operations had been totally affected by the pandemic also saw the greatest improvements, supporting the point that the pandemic motivated organizations to adapt their clinical trial processes - and for the better.

Clinical trial outcomes have changed for the better

Respondents report multiple improvements across the clinical trial process, with more than a third (37%) ranking better outcomes of clinical trials as within the top three areas of improvement. 36% say recruitment and enrollment into trials were also better, as well as better patient experiences. The same proportion cite greater use of remote technologies, spurred by the pandemic, to decrease site burden. 34% report a greater uptake of remote technologies to decrease patient burden and allow them to spend less time in the clinic and more time at home.

References:

5 - https://www.who.int/news/item/23-04-2021-covid-19-continues-to-disrupt-essential-health-services-in-90-of-countries

"Clinical development is being transformed by the use of digital technologies."

Pharmaceutical company, Germany

"Incorporating technology to reduce patient burden can help enhance clinical trials."

Biotechnology company, UK

The greatest areas of improvement vary across geographies. In Germany, about half of respondents (48%) highlight greater flexibility and engagement with regulators throughout the clinical trials process as one of the top three areas of improvement. Respondents in France and Switzerland report greater uptake of remote technologies to decrease site burden (46% and 44%, respectively). In the UK, patient experience was seen as one of the three main areas of improvement (45%), a promising outcome, given how much a positive patient experience can improve trial outcomes.

Improvements seen across clinical trial processes due to the pandemic

Total	Germany	France	UK	Switzerland
37%	48%	46%	45%	44%
Better outcomes of clinical trials	Greater flexibility and engagement with regulators	Greater uptake of remote technologies in clinical trials to decrease site burden	Better patient experience	Greater uptake of remote technologies in clinical trials to decrease site burden

Figure 2: In which of the following areas have you seen the biggest improvements across clinical trials processes, as a result of the pandemic? Combination of responses ranked first, second and third [393], based on those which have seen improvements as a result of the pandemic, showing top improvements, split by country, omitting some answer options

"We can use big data and data modeling to assess the likelihood of success. Virtual technologies can link and integrate the different components of the study and capture more meaningful and relevant data - accelerating the ones with greater promise and reducing spend on programs that show less promise."

Hospital or clinic, Switzerland

Improvements could stand the test of time

Nearly all surveyed respondents (99.7%) believe that all or some improvements to the clinical trial process as a result of the pandemic are here to stay.

There are a number of reasons why some respondents believe that not all improvements will become permanent though. Reliance on historical systems and processes are reported to be a key barrier by just over half of respondents (51%). This is a notable pinch point in France (64%) and the UK (49%). This is problematic, considering all pharmaceutical companies will in one way or another be dependent on existing systems.

Another factor perceived by respondents as a potential barrier is patient preferences, with nearly half (47%) of those surveyed citing this as an issue. This suggests organizations might have to invest in educational tools to introduce patients to new ways of participating in clinical trials and to explain how technology can help during the trial process and lessen the burden on them.

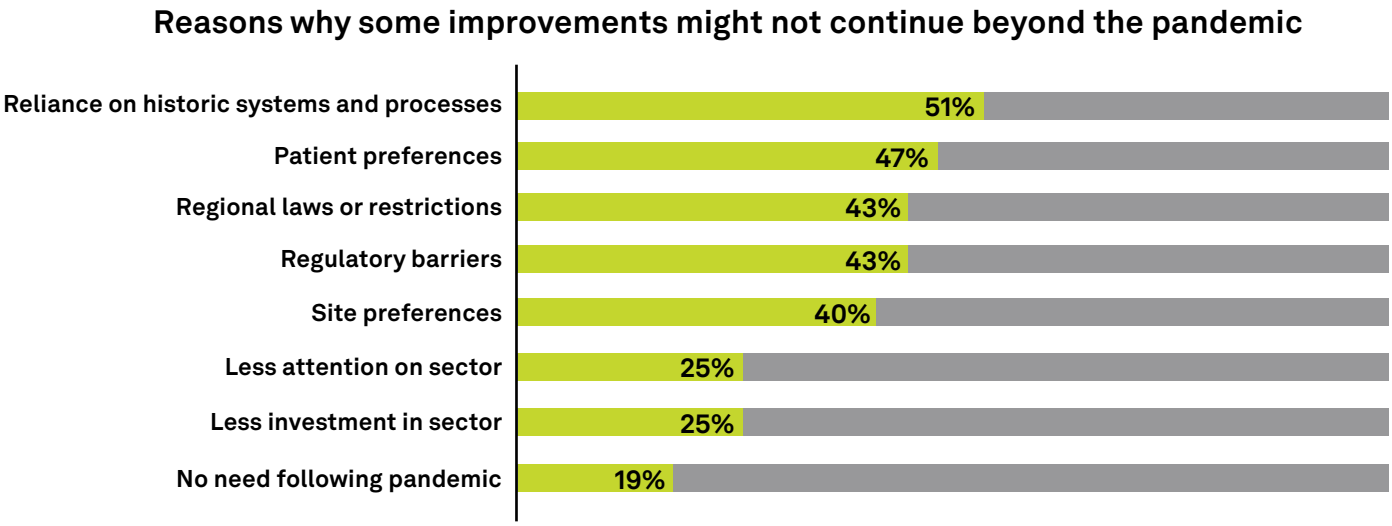


Figure 3: Which of the following are reasons why you don't believe that all improvements seen across clinical trials processes within your organization/for your customers will continue beyond the pandemic? [150] Based on those that don't believe all improvements will continue beyond the pandemic, omitting some answer options

The power of technology

A virtual world: Adopting technological advances

The four surveyed countries view themselves as being technologically advanced and early adopters of new technologies in clinical trials, such as remote monitoring tools, electronic patient diaries, and technologies to randomize patients and supply treatments (93% of respondents believe they are global leaders or early adopters).

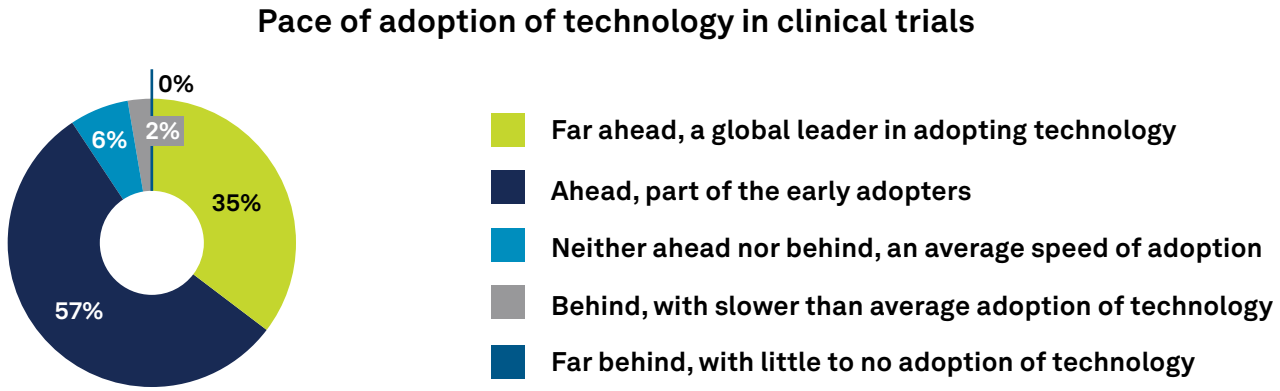


Figure 4: Do you believe that your country is ahead or behind other countries in adopting the use of technology in clinical trials? [150], omitting some answer options

All respondents report that clinical trials in their country rely on technology, or digital tools and solutions, in some capacity. 92% of those surveyed say clinical trials in their country *always or frequently* rely on technology. This highlights the shift over the past few years towards adopting digital innovations, further accelerated by the pandemic.

"Adopting a digital mindset around technology, collaboration, and advanced work practices is essential."

Pharmaceutical company, Germany

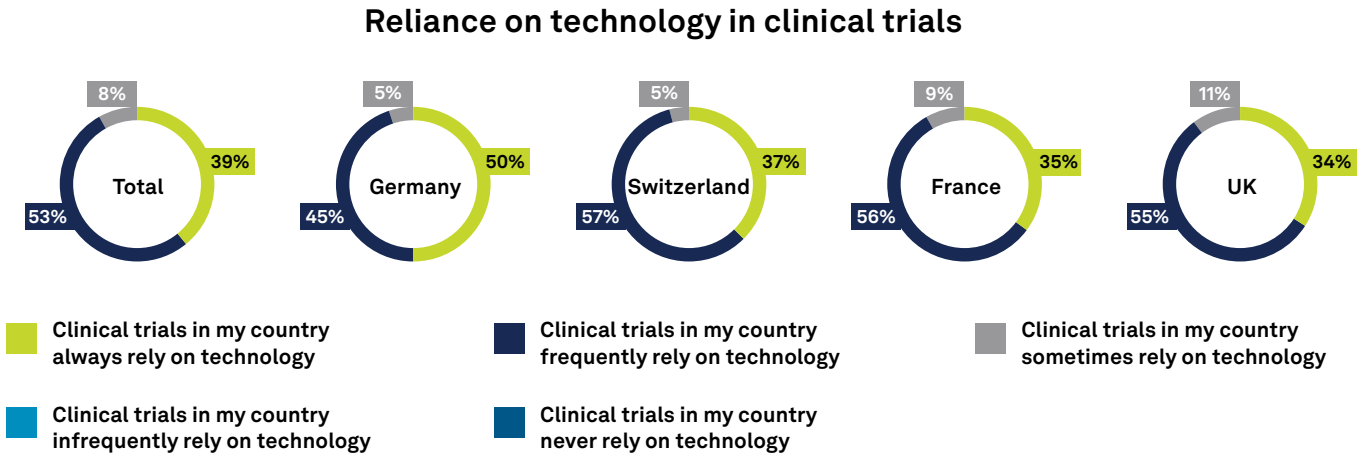


Figure 5: Do clinical trials in your country rely on technology or digital tools and solutions? [400], split by country

"It's important to prioritize and optimize the data accrued at each stage of the cycle. An adaptive design approach will increase the success and highlight deficiencies earlier. Too many trials are flawed in design which ultimately delay the time to approval."

Hospital or clinic, Switzerland

The rise of decentralized clinical trials

DCTs have been around for some time, but the pandemic has increased their wider adoption, as organizations needed to rethink their operations to fit in with the 'new normal'. The use of DCTs is generally expected to become even more widespread, aligning with the survey's findings that they are becoming increasingly commonplace and will continue to grow in adoption. Respondents note that the average number of studies including at least one decentralized technology before the pandemic was 43%, the current average is 55% and the predicted average in five years' time is 66%.

Decentralized clinical trials (DCTs) - also termed "direct-to-participant trials" or "virtual" studies - are characterized by less dependence on traditional research facilities for data collection. DCTs leverage "virtual" tools, such as telemedicine, sensory-based technologies, wearable medical devices, home visits, patient-driven virtual health care interfaces, and direct delivery of study drugs and materials to patients' homes. Source: NIH.gov

> ***"Drug development can be improved by expanding the use of virtual clinical trials. Some aspects of the trial can be conducted remotely and can incorporate both centralized and decentralized models. And use the incoming data as the trial develops and be willing to adjust and change where necessary."***
>
> **Academia (within healthcare), France**

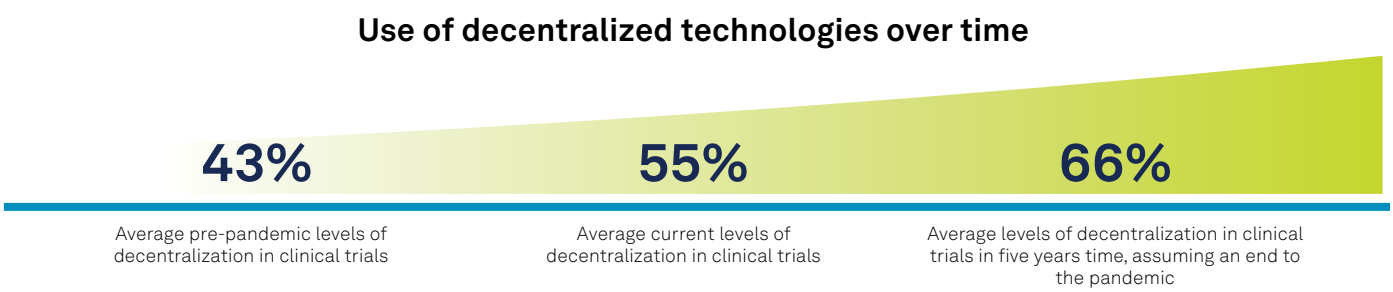


Figure 6: Approximately what proportion of your organization's or your customers' studies have, or will, include at least one decentralized technology (or digital tool/solution) over the following timeframes? [400], showing average scores

All respondents say there are clear benefits to leveraging a DCT approach, while 95% reported DCTs to be standard practice. The critical benefits listed by respondents include better compliance and governance adherence (42%), improved patient recruitment and retention (41%), and improved patient experience and overall engagement (41%).

This demonstrates that there's room to use decentralized trials further, and organizations believe that it's an approach worth investing in.

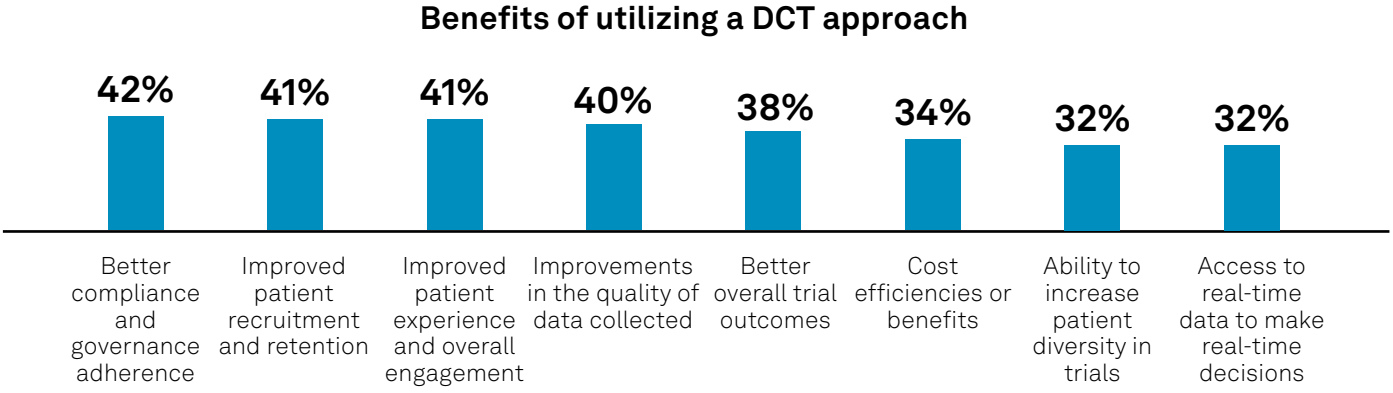


Figure 7: Which of the following benefits do you believe your organization, or your customers have experienced, or would experience, as a result of using a DCT approach? [400], omitting some answer options

When asked how technology can positively impact the patient experience, respondents highlight that it can help with the delivery and administration of drugs and treatments to patients (39%), collecting patient data (38%), and enhancing patient data protection and safety (37%).

Without technology, collecting patient data can be a time-consuming process with more room for human error and risks of patient data being lost. Technology can help these processes be more streamlined, properly audited and easier to manage, so that resources can be saved such as costs and time, or focused on other areas, like patient engagement. [6]

References:

6 - https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.119.040798?cookieSet=1

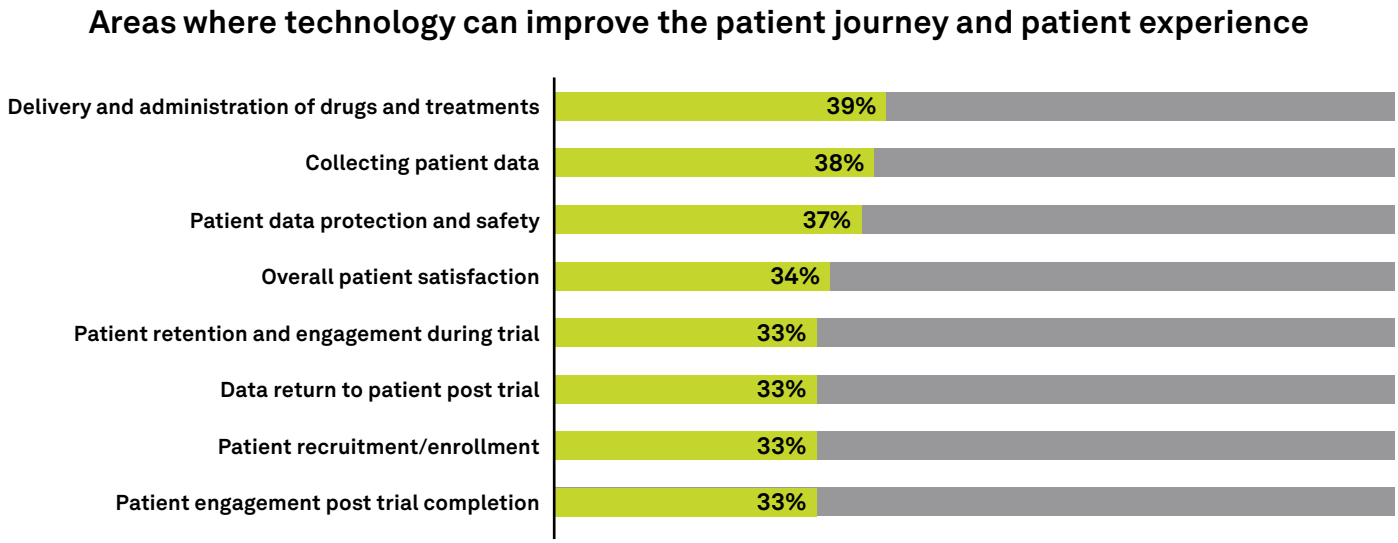


Figure 8: At what stage(s) of the patient journey do you believe technology has the greatest positive impact on improving patient experience? [400]

"The industry needs to make better use of digital technologies and new models to improve outcomes, accessibility and reduce cost. Virtual trials will increase patient participation and access and improve the patient experience."

Academia (within healthcare), Germany

However, in order to successfully increase DCT adoption, respondents note that organizations need to consider the integration of their existing technologies (46%), as well as the investment in new ones (45%). These factors, as well as support from technology vendors (43%), can help organizations on their way to a more seamless DCT approach. Respondents also note the importance of effective employee training (40%) and regulatory flexibility and guidance (40%).

Respondents were also asked about what they thought patients would begin to expect from clinical trials. Nearly half (48%) cite increased use of remote tools and solutions, which could include patient monitoring, ability to receive study medication at home and data collection, all of which go hand in hand with a decentralized approach to trial design.

Barriers to DCT adoption: Investing for the future

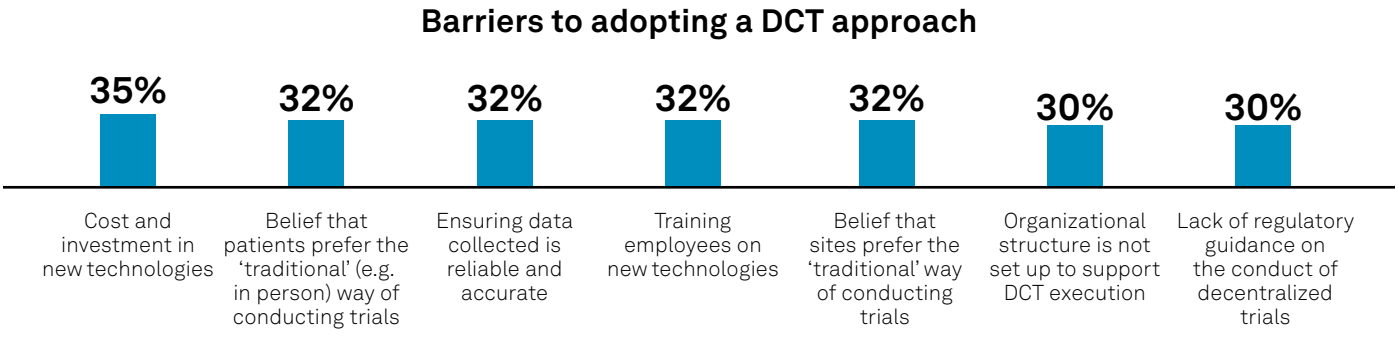


Figure 9: Which of the following have been or will be barriers to decentralizing trials and using clinical trial technologies within your organization or for your customers? [400], omitting some answer options

On the whole, respondents report that the cost and investment of new technologies, patients and sites preferring traditional clinical trial methods, and ensuring reliability and accuracy of data, as some of the main hurdles to investing in DCTs.

> ***"It is imperative that more investment is made in new technologies to conduct clinical trials and develop drugs."***
>
> **Healthcare regulatory body, UK**

However, the key barriers varied by country. Respondents in the UK cite organizational structures not set up to support DCTs as a stumbling block (38%). Those based in France report high costs (38%) and accuracy and reliability of data (38%) as the key barriers. In Germany, 35% of respondents say a lack of regulatory guidance over the use of DCTs coupled with employee training were the main hurdles. Swiss-based respondents say a reluctance to change (40%) is holding back more widespread use of DCTs, with clinical trial sites preferring traditional ways of conducting trials.

Need for a supportive regulatory environment

Overall, respondents are more likely to report that the regulatory environment in their country is somewhat supportive of the use of technology in clinical trials (57%). Germany is the only country where more than half (52%) note that the regulatory environment in their country is largely supportive. Greater support from regulatory bodies could see organizations leveraging technology more and improving their clinical trial processes and outcomes as a result of the benefits previously outlined.

While there is a great deal of enthusiasm about DCTs and the benefits they offer, there are also barriers preventing broader and faster uptake. Companies and regulators must work to overcome these barriers or risk being left behind - and communication and collaboration are key.

> ***"Pharmaceutical companies and clinical research organizations need to understand the regulator's role and responsibilities. We certainly want to enable innovation and streamline trial approvals, but also take proportional risk into consideration. With good communications, we can work alongside one another."***
>
> **Healthcare regulatory body, France**

> ***"Regulatory frameworks, which may seem as adding a burden, are necessary to improve safety and efficacy. Our role is to protect the patient, but we are open to improving trial conduct and streamlining the regulatory procedures."***
>
> **Healthcare regulatory body, Germany**

The increased focus on patient centricity

Putting patients at the core of the clinical trial process

The large majority of respondents (92%) believe clinical trials are more patient-centric than ever. The pandemic forced organizations to rethink the way trials are run to ease the burden on patients, with more than half of respondents (54%) saying that trials are now slightly more patient-centric than before the pandemic and more than a third (39%) say they are much more patient-centric.

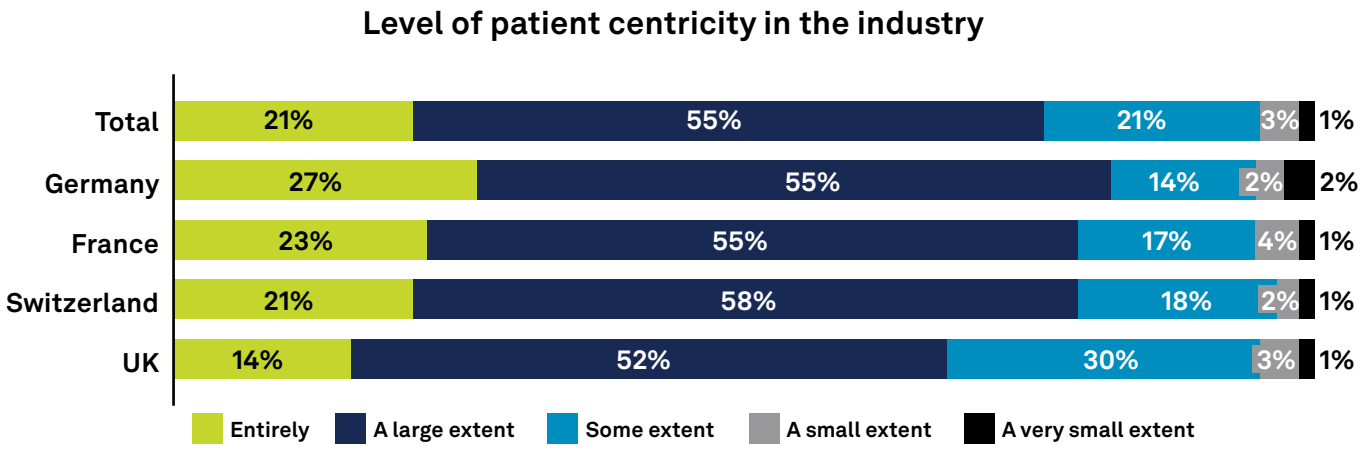


Figure 10: To what extent do you believe the industry has achieved patient centricity? [400], split by country, omitting some answer options

"Clinical trials and drug development processes can be further improved by considering patient feedback from the study and incorporating it into the final product design."

Pharmaceutical company, Germany

Barriers to patient centricity: Huge potential going forward

Respondents from the UK note that regulatory framework and restrictions are preventing clinical trials from being more patient-centric (59%), while Switzerland and Germany point out that sites or researchers are perceived to be resistant to changing traditional clinical trial conduct (52% and 50%, respectively). In France, respondents cite a lack of engagement with patients post-trial completion (46%). Addressing these barriers, especially the resistance to change, will be crucial if clinical trials are to become truly tailored to suit the needs of patients.

"Taking a holistic look at the patient experience during the study design can help enhance clinical trials."

Medical or healthcare technology company, UK

"The planning process needs to be improved. The industry needs to make better use of digital technologies and new models to improve outcomes, accessibility, and reduce costs. Virtual trials will increase patient participation and access and improve the patient experience. Agreeing on objectives with third parties and involving the regulator at the earliest stage, so that you know what they need, is vital."

Academia (within healthcare), Germany

Furthermore, when asked how clinical trials and drug development can further be improved, respondents note several areas for consideration. These include more use of AI, technology, and computer simulation (30%), more focus on patient centricity (18%), and improvements to process-related activities within a trial (15%).

Electronic consent as a key tool to support DCTs

Nearly all respondents (97%) confirm their organizations are using electronic informed consent (eConsent) to enroll participants in clinical trials. Across the countries surveyed, 63% of respondents report that they have been using eConsent for one to two years and 32% for less than a year. There are clear benefits to using eConsent and its use is rapidly increasing.

> Electronic informed consent (eConsent) refers to using electronic systems and processes that may employ multiple electronic media including text, graphics, audio, video, podcasts and interactive web sites, and card readers, etc., to communicate information related to the study and to obtain and document informed consent. Source: NIH.gov

eConsent increased substantially during the pandemic for practical reasons, given lockdowns and social distancing measures. But the tool has other benefits, too. Respondents say eConsent improves regulatory compliance (44%), improves patient retention (43%) and makes for a better patient experience (43%). It helps educate trial participants, explains what they can expect from the trial and allows them to flag any questions or concerns, creating a digital audit trail of the patient experience.

The future of clinical trials

When asked what the key industry trends would be over the next five years, patient centricity came out on top, with 42% of respondents ranking this area within the top three key trends. Increased use of simulation technologies and artificial intelligence (40%) and improved access to clinical trials (38%) were also noted as important.

"Clinical trials can be improved by increasing patient engagement, gaining deeper insights, innovating patient care and implementing processes to realize efficiencies."

Biotechnology company, France

"A greater emphasis on the use of computer simulations could help improve the efficiency of all phases of drug discovery and development."

Contract Research Organization, Switzerland

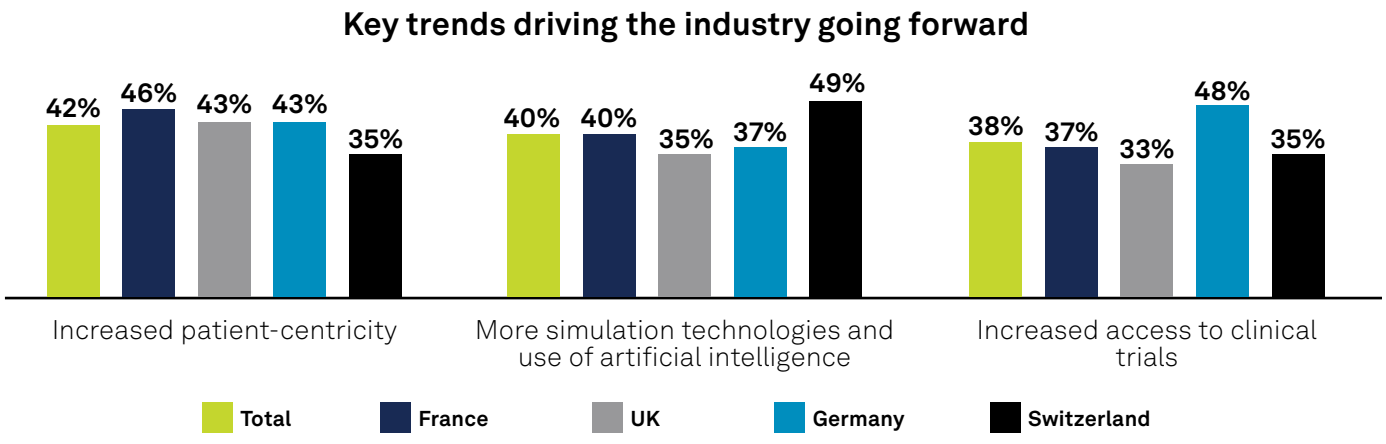


Figure 11: What do you see as the key trends driving the clinical research industry over the next 5 years? Combination of responses ranked first, second and third [400], split by country, omitting some answer options

When asked what technology holds the most promise in the future of clinical research, more than a third of respondents (36%) point to artificial intelligence within the top three areas, which has the opportunity to improve trial design, site selection, and provide performance analytics, among other things.

"Encouraging open innovation, facilitating cross-sector collaboration and outsourcing drug discovery is key to improving clinical trials."

Pharmaceutical company, Germany

"By utilizing AI properly, drug discovery has the potential to be revolutionized. It is essential for expediting drug development and will lead innovation."

Biotechnology company, UK

Summary

The pandemic radically accelerated the shift and progress of clinical trial conduct, creating unprecedented opportunities for the industry to evolve. Such change has been facilitated, in large part, by the increased use of digital tools and solutions and leveraging DCT approaches, which creates a more streamlined and efficient operating model with the patient at the center. Even though the pandemic hit the industry hard and initially halted clinical research, it required companies to re-evaluate their trial designs and methods to collect data, and adapt them. In turn, this has led to improvements across their processes - and many of these improvements are here to stay.

While the pandemic acted as a catalyst for change, there are still opportunities for the sector to evolve, such as introducing more patient-centric practices, furthering use of technology, and leveraging artificial intelligence for better decision-making. By continuing to challenge current models, investing in new technologies and collaborating across all stakeholders, the industry can further improve clinical trial processes and outcomes, all for the benefit of those at the heart of the process: patients.

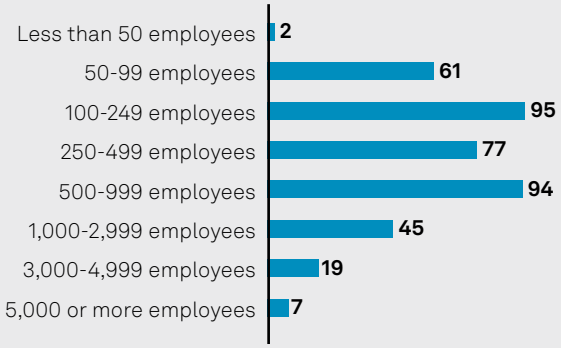
Methodology and demographics

Four hundred C-level, senior management and mid-level management respondents working in the clinical research field were interviewed between March and May of 2022. They were based in the UK, France, Germany and Switzerland. All interviews were conducted using a rigorous multi-level screening process to ensure that only suitable candidates were given the opportunity to participate. Further detail on the breakdown is available in the Appendix.

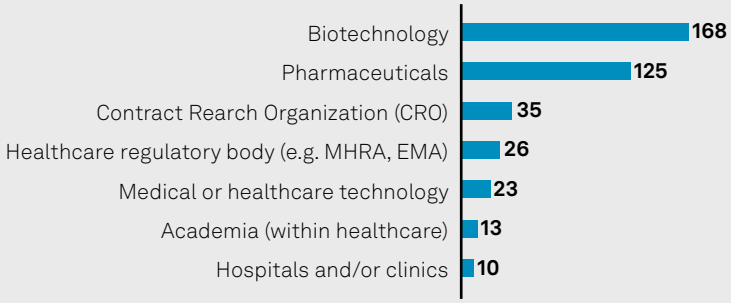
Respondents by country

UK	France	Germany	Switzerland
125	100	100	75

Respondents by organization size



Respondents by organization sector



Respondents by position

Board member; C-level	Senior management, senior manger of unit, function or department	Mid-level management, manager of team or group
122	241	37

About Medidata

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