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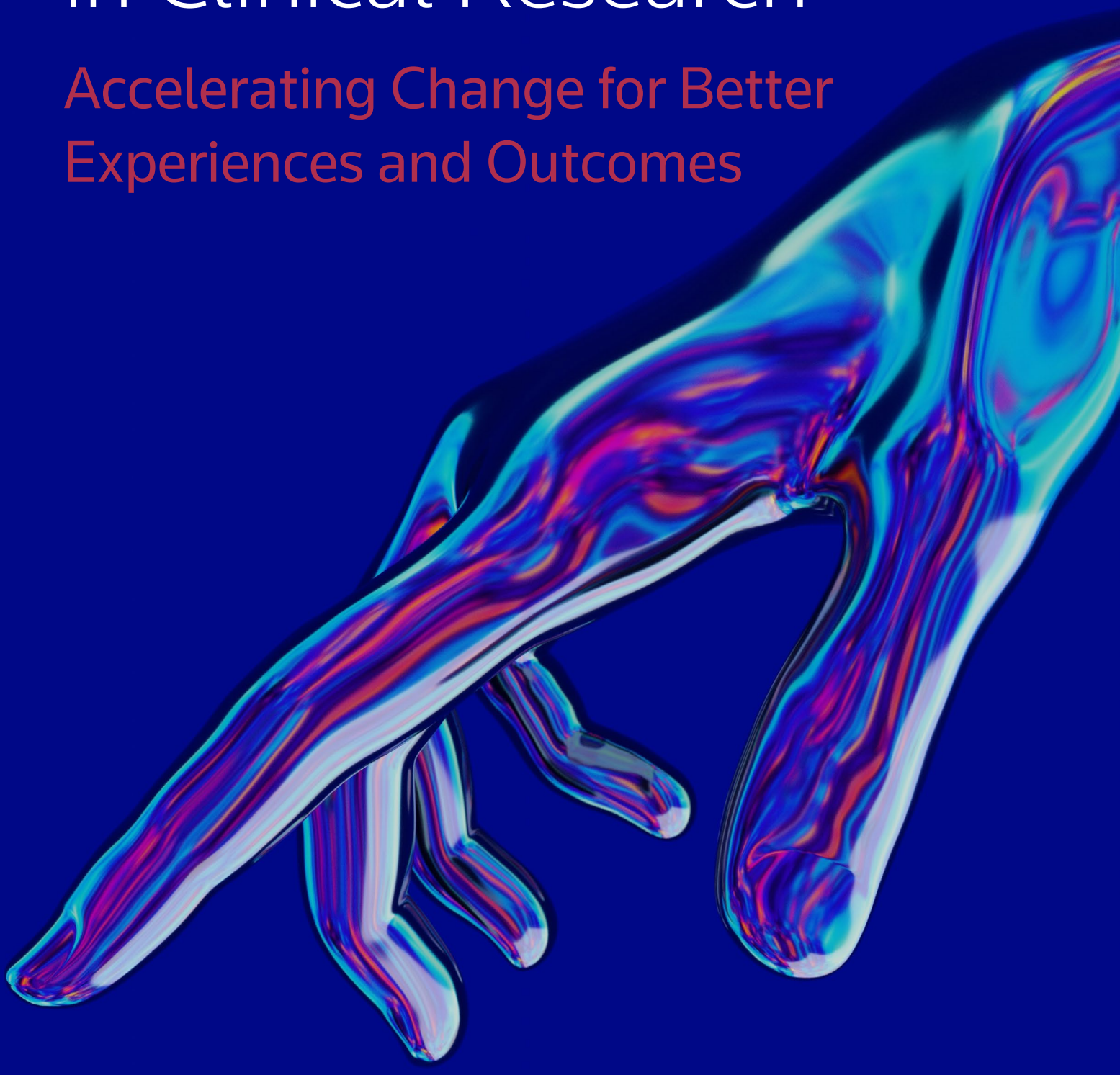
Microsoft

Digital Transformation in Clinical Research –

Accelerating Change for Better Experiences and Outcomes



Executive summary

Digitizing clinical research can do more than just solve some of pharma's current R&D problems. Much broader benefits beckon. In a world where clinical data is used to drive continuous improvements in evidence-based medicine, patients can receive improved access to treatments, a personalized care journey and better outcomes.

Achieving these aims requires solving the problems created by siloed data, disjointed systems, administrative burdens and fragmented care delivery that bedevil today's clinical research ecosystem. A big part of the solution to many of these issues is harnessing the potential of digital transformation. A recent survey by Reuters Events Pharma of over 300 globally-distributed industry professionals shows that adapting to and leveraging digital technology is now the top priority in clinical research.

Pharma sees great opportunity to use remote and digital technologies for far more than merely digitizing and modernizing clinical endpoints. Multiple converging technologies – including artificial intelligence (AI), machine learning (ML) and blockchain – are arguably set to reshape R&D from target molecule identification, through preclinical, phase III and observational studies.

The potential of AI, ML and data sharing is vast when applied to genomics, adverse events and risk monitoring, clinical trial access and diversity, retention and the knock-on effects on protocol and program design (such as relaxing exclusion criteria around comorbidities thanks to predictive analytics).

"The challenges faced by all in developing treatments and vaccines for Covid-19 has changed the landscape forever."

Peter Mesenbrink, Executive Director of Biostatistics at Novartis

Introduction

According to the World Economic Forum, the healthcare industry stores more than 2,300 exabytes of healthcare information, with 97% of all data produced by hospitals each year going unused, and clinical trial data routinely not being utilized when studies end [1]. Used effectively this could drastically improve the standard and efficiency of care but the industry continues to struggle to unlock the value it contains.

Sponsors and study sites are struggling with inflexible and disjointed data capture systems, heavy administrative burdens, fragmented care delivery and staff burnout, whilst simultaneously attempting to cope with the rise of digital endpoints, devices and wearables, mobile health and a whole host of innovations that are creating an enormous enormous volume of new data sources.

The pandemic forced new ways of using existing technologies and collaborating so that frontline workers and patients were able to continue healthcare studies with virtual visits, medical sensors, and low-touch/no-touch approaches, including new ways to deliver clinical supplies directly to participants. Out of necessity, remote technologies and decentralized trials, which had been discussed for years, were suddenly thrust front and centre of the stage.

The development of new vaccines, the fastest in the history of medicine, for example, was in part thanks to the flexibility offered via Cloud-based tools[2].

Digital transformation was invaluable in helping healthcare organizations balance the demands on their time and resources, with non-urgent patients kept under remote monitoring at home, while improving overall care and outcomes[3].

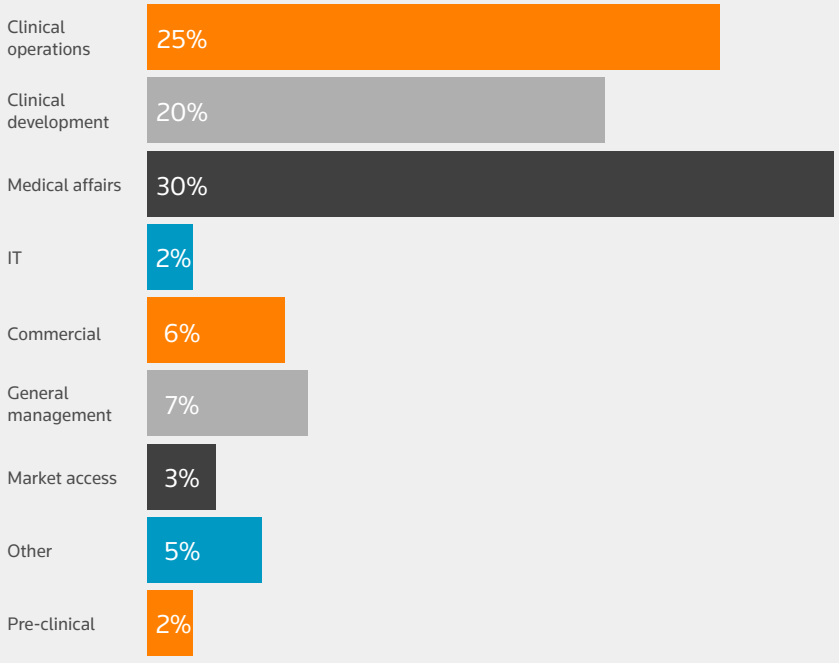
Organizations are now collaborating to a much greater degree to better harness digital technology in clinical trials, with consortia such as TransCelerate BioPharma and the Decentralized Trials and Research Alliance (DTRA) playing an important role, along with regulators, industry innovators and technology providers.

According to a March 2022 survey by Reuters Events Pharma of 312 globally distributed industry professionals, 88% of whom are in pharma or biotech and roughly two-thirds of whom are director-level and above, these industry consortia are impacting the end-to-end clinical trial process in multiple ways.

Who we spoke to for this survey

Q5. Which of the following best describes your role?

Q6. Which function are you most closely aligned with?



They are doing this by leading data sharing and standardization initiatives that will provide easier and broader access to information that historically has been difficult to obtain, by driving changes that will improve the overall clinical trial process, such as decentralized clinical trials, helping find and recruit more diverse patient populations, and developing more tangible solutions to leverage advanced technologies to accelerate the drug development process.

Craig Lipset, Advisor and Founder of Clinical Innovation Partners and Co-Chair of the Decentralized Trials & Research Alliance, describes how organizations in the past two years have been "more receptive to new tools and technologies than typically in the past, particularly those that are seen as mitigating the risk of disruption created by either Covid or other things that may stand in the way of a patient getting to a site."

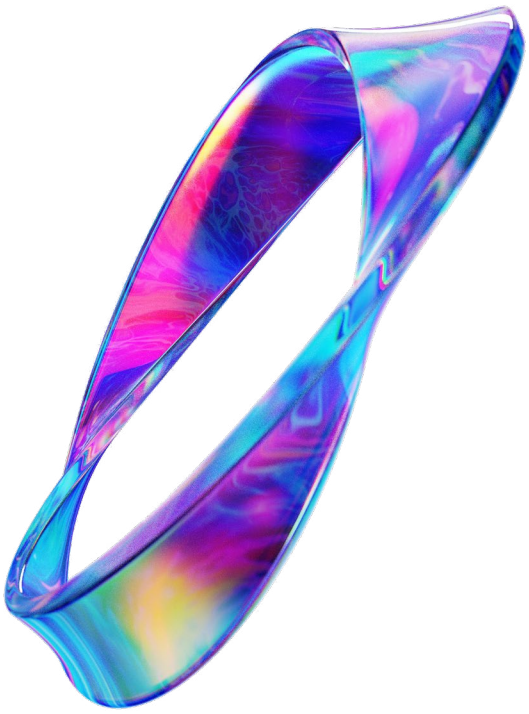
There has been, Lipset adds, "a trend in recent months towards normalizing the changes of the past two years, managing change, normalizing processes and operating models in these areas."

But there's a long way to go, according to Bill Illis, Global Head of Collaboration and Technology Strategy for Clinical Development and Analytics at Novartis and Workstream Lead for the Digital Data Flow (DDF) initiative at TransCelerate. Its aim is to modernize the R&D ecosystem, with an emphasis on shifting from managing programs to leveraging opportunities for multi-agency and multi-company opportunities[4].

"We´re starting from a foundation that I would argue is not very strong, with regards to the ability to capture and use digitized data, and also not very strong with regards to exchanging data between systems, both within organizations and between organizations," says Illis. "At the same time, we´re faced with more systems in the clinical development process, in an increasingly complex landscape, and these systems now are often being stitched together with manual processes."

Despite the many practical hurdles and the work required to improve here, we can draw from numerous inspirational examples of how technology has been used in healthcare and clinical research in the past two years, to see how the digitization of healthcare data may shape the future.

Peter Mesenbrink, Executive Director of Biostatistics at Novartis summarizes the current situation: "The challenges faced by all in developing treatments and vaccines for Covid-19 has changed the landscape forever[5]."



"There has been a trend in recent months towards normalizing the changes of the past two years, managing change, normalizing processes and operating models in these areas."

Craig Lipset, Advisor & Founder of Clinical Innovation Partners and Co-Chair of the Decentralized Trials & Research Alliance

Tech adaptation is the top priority for life sciences

Adapting to digital and remote technology for use in clinical trials is at the top of the agenda of the life sciences industry with 52% of respondents identifying this as a key challenge, followed by speed of trial recruitment (44%), and access to non-traditional data sets, such as those associated with wearables, real-world evidence and public data sets (39%). Respondents also expect adaptation to digital and remote technology to remain the top key challenge in five years' time, with access to non-traditional data sets anticipated to be a close second.

Adapting to digital and remote technology for use in clinical trials is at the top of the agenda of the life sciences industry, according to the survey.

What are the top 3 key challenge areas in clinical trials operations? (Q9)

Q9. What are the top 3 key challenge areas in clinical trial operations?

1. Demonstrate that adaptation to digital and remote technology is the top priority.

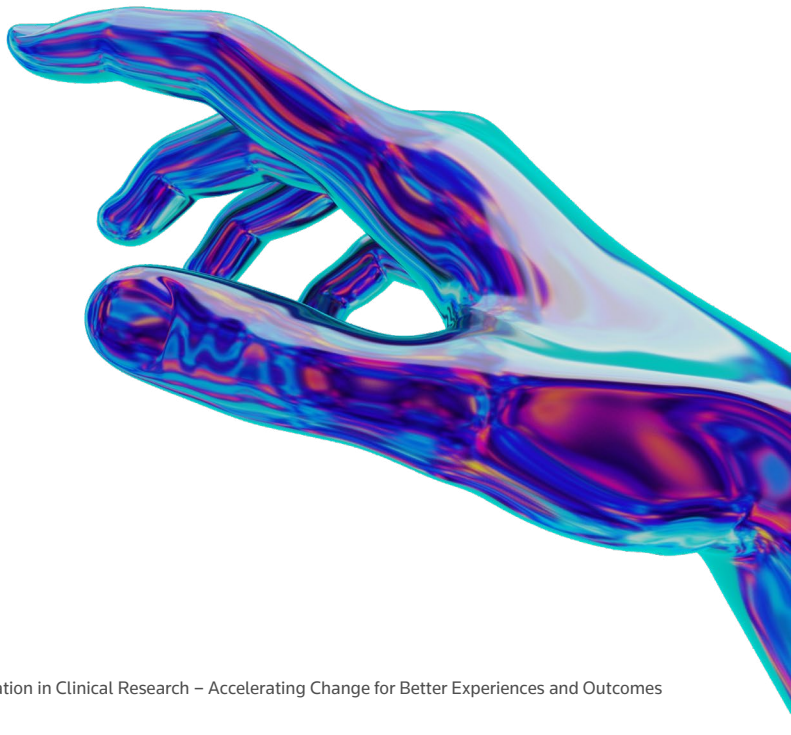
52%

2. Speed of trial recruitment.

44%

3. Access to non-traditional data sets, such as those associated with wearables, real-world evidence and public data sets.

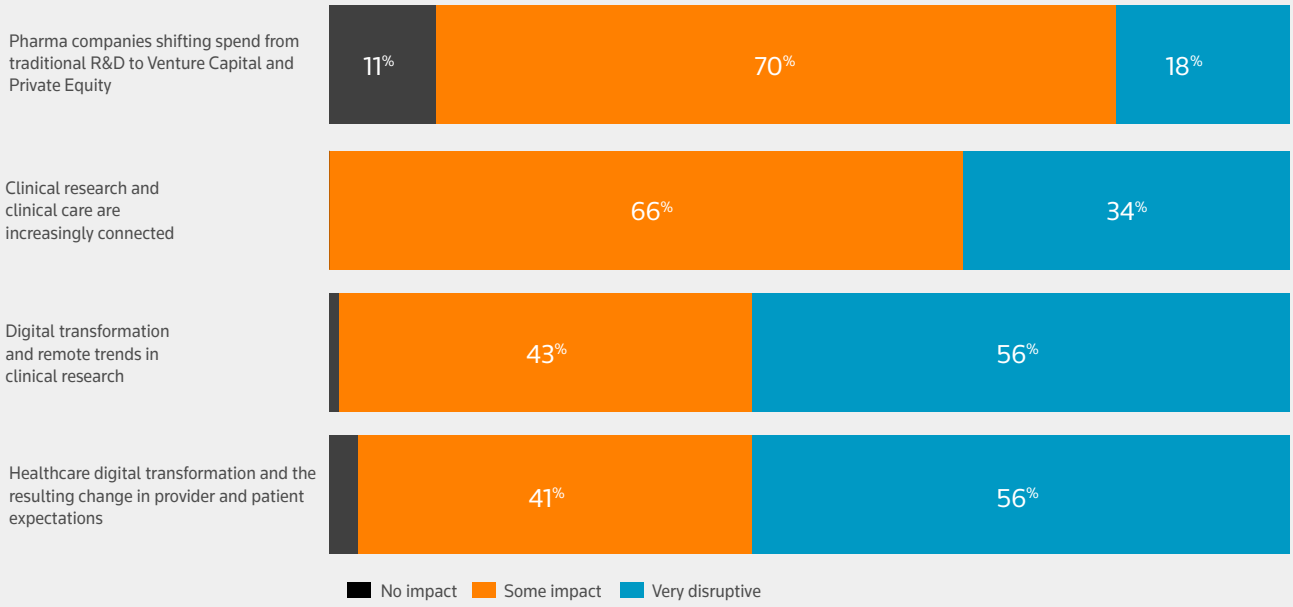
39%



These results aren't surprising considering how digital and remote technology in clinical trials have become more mainstream, putting both adapting to technology and accessing non-traditional data sets firmly at the top of most of the survey respondents' agendas.

In fact, when asked about the anticipated impact of various industry trends on clinical operations in the next two years, almost all respondents (98%) anticipated a "very disruptive" or "somewhat disruptive" impact as a result of both digital transformation and remote trends in clinical research, and digital transformation in healthcare.

Q8. How much of an impact do you expect the following trends to have on clinical operations in the next 2 years?



Oscar Segurado, Chief Medical Officer at ASC Therapeutics explains that the adoption of technology in an ongoing gene-therapy trial has caused data points per patient to increase exponentially, and in a few years, once data collection is complete, sourcing tools for data processing will be needed to allow effective data visualization once data collection is complete.

"We expect to receive up to one million data points per [patient?] over the course of this study. All this data needs to be assessed. Data management is something that´s absolutely crucial for us and we rely on our contracted CRO to handle data management.

"We´re still collecting the data, but when we start putting together publications to show our data and making decisions based on the data, at that moment we will need to ensure that we have the right tools. We are a few years away from deciding how we´re going to do that, but I´m a big believer in the visualization of data, this is front and center. The first step is data management, inputting the data, and then you can visualize it."

Overcoming the barriers to rapid adoption

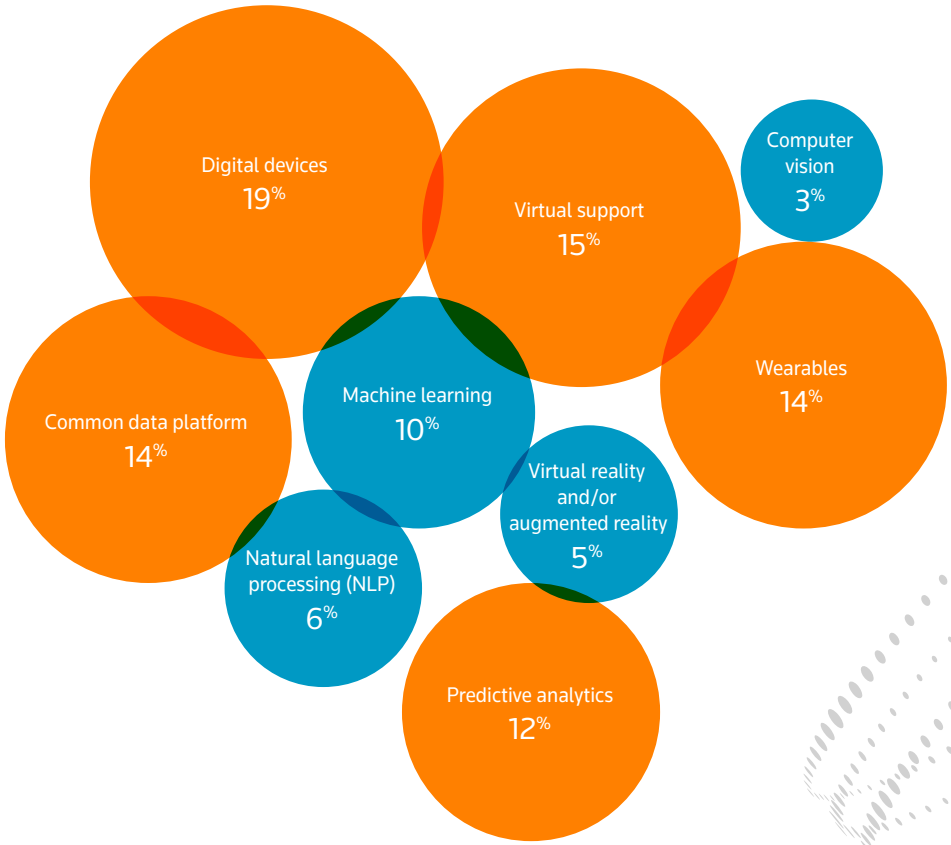
When asked about the technologies respondents were currently using in trials, they cited digital devices as the most widely used of 11 options given, with 51% of respondents indicating their use in trials to date. Virtual support (37%), wearables (36%), a common data platform (35%), predictive analytics (29%), machine learning (27%), and natural language processing (14%), are also being used by a significant proportion of respondents, with less common technologies such as virtual or augmented reality (8%) and computer vision (8%) also being reported.

The survey also revealed that in five years´ time only 5% of respondents anticipate not using non-traditional data sets from wearables, real-world evidence and public data sets. Most respondents (55%) anticipate the use of non-traditional data sets will be "very prevalent" or "somewhat prevalent" (40%) in five years' time. Currently the use of these data sets was described as "somewhat prevalent" by the majority of respondents (55%), "very prevalent" by 15% of respondents, and "not prevalent" by 24% of respondents.

Whether or not to implement digital technology to help with trial data capture as well as the practical logistics of trials is a question that most in clinical development are wrestling with. Not all prospective technology partners are equal in this respect, says James Chennells, Head of Clinical Trial Technology at Bayer.

"Often technology companies that are more familiar with clinical trials are more upfront and aware of challenges than others, because those coming from outside the industry often don't know that certain challenges exist. So, the solutions of outsiders may appear shinier and better, but actually, they´re not."

Q11. Which of the following technologies have you used in your clinical trials? Select all that apply.



A potential partner's understanding of how its technology fits into the trial is therefore important, says Chennells. "Typically, the challenges aren't fundamental issues with the technology, they're more about the implementation and application to clinical trials. For example, how their application for a given trial needs to work in conjunction with what needs to be submitted for ethics committees or whichever part of the administrative process."

The ability of new technology to help with the fine-grained logistical aspects of trials that could ease the patient burden is also being widely explored, he adds. "How could technology help a patient go to their closest hospital that has the right equipment (such as a CT scan or blood tests), which might only be 20 minutes away, rather than having to travel two hours to go to a clinical trial site?"

The industry is also widely exploring the potential for hybrid trials to decrease patient burden and offer patients greater flexibility, such as letting them choose not to come to a trial site, if their remotely monitored safety data meets certain standards.

In the survey 93% of respondents either strongly agreed or somewhat agreed that technology would be the main driver positively impacting remote monitoring support. Furthermore, 88% of respondents either strongly agreed or somewhat agreed that technology would be the top driver behind enabling decentralized clinical trials (DCTs).

A question remains about the extent to which technology can help meet some of the practical challenges of running clinical trials that are centered around bricks and mortar sites, however.

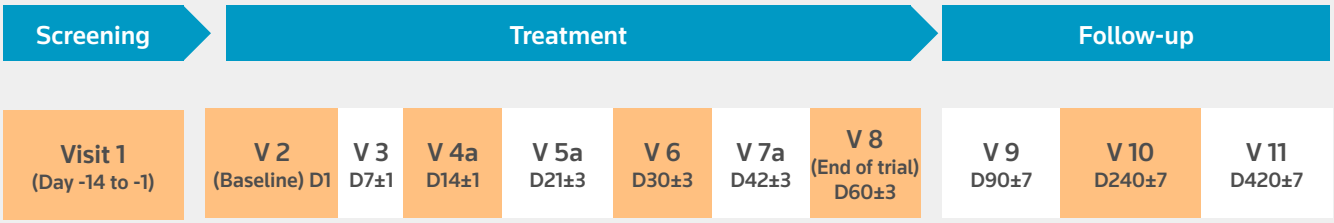
"How could technology help a patient go to their closest hospital that has the right equipment (such as a CT scan or blood tests), which might only be 20 minutes away?"

James Chennells, Head of Clinical Trial Technology at Bayer

The collaboration announced in February between Medable and CVS Health pharmacies, is an example of evolving partnerships that could go some way in overcoming such obstacles in the future. The deal seeks to combine Medable's decentralized and hybrid clinical trials platform technology with the extensive community reach of CVS Health in the US.

Alison Holland, Head of Decentralized Trials at Medable explained how the company has been improving the patient experience in hybrid cancer trials. "Oncologic drugs tend to be relatively toxic. Doing a decentralized oncology study doesn't necessarily mean that you do everything remotely, and it doesn't necessarily mean that the patient never comes to site. It means that we're able to say: "OK, we've collected enough safety data, you could continue to come to the hospital if you prefer or you could have some of your visits at home (depending on the protocol)."

Mock hybrid study visit schedule schedule, enabled by remote safety monitoring and visit flexibility for patients to choose to be visited at home.



There is also a high priority in healthcare to introduce or continue to use virtual, hybrid or distance care interactions, which will help with the mission of shifting to hybrid or decentralized trials as the offerings develop. The more virtual care options, with remote or automatic monitoring of patients, the less trials are tied to a physical site or physical location, which increases access to clinical trials for those unable or unwilling to travel to sites that are often so far away.

But driving this change has required challenging established approaches and mindsets. Taking e-consent as an example, Holland explains how continuing with old ways and shying away from the hurdles brought by new technologies can be convenient in the short term, but this approach doesn´t bring long-term benefits.

"It's very easy to pick up a piece of paper and continue using a wet ink signature. We all know the flaws and the quality issues associated with e-consent and the lack of comprehension and understanding. But, to address that, you have to invest a little bit more effort up front, to get through the learning curve, and get to all those benefits on the back end.

"Benefits [include] having digital data in a single system which is immediately available for recall, which can be transferred to various different places, so there´ll be an awful lot more that you can do with it, but you've got to go through that change hurdle first."

Daniel Carchedi, Senior Director of Business Development and Strategy for Health & Life Sciences at Microsoft explains his take on the current situation: "I've been in this industry for my whole career and its slow-moving nature can be frustrating. But the pandemic has accelerated and changed that mindset. We made progress in months versus what would have taken years in terms of adoption of technology and even the speed of adoption. Seeing how the vaccines were developed is one clear version of that. And now, looking at clinical trials and digitization of them will start to recognize that.

"It's here, and we've got to embrace it. And adoption is not a technology problem. Now it's more of a leadership problem in terms of transforming the industry, in my opinion."

"You have to invest a little bit more effort up front, to get through the learning curve, and get to all those benefits on the back end."

Alison Holland, Head of Decentralized Trials at Medable

Digital transformation: The future of clinical trials

A new breed of software platforms that facilitate DCTs

Multiple factors are due to play a role in shaping the future ecosystem of clinical trials, from converging technologies such as AI and ML to a shift in societal values to ones of sharing and collaboration, both between organizations and between corporate organizations and governments.

Microsoft sees consortia playing a vital role in the future. According to Carchedi: "Consortia will be leveraging technology to set the data standards, how data is adjusted, how it´s submitted and even working with regulatory bodies, and I think industry needs to pay attention to that space and those relationships. It´s not possible for consortia to create blueprints for clinical trial design across the board, but it´s certainly likely that they´re going to create guidance and guidelines."

Another important factor is the new breed of software platforms that help facilitate decentralized clinical trials (DCTs). One such example is Castor, a DCT platform designed to enable researchers to capture and integrate high-quality data from any source on one compliant platform.

Founded by CEO Dr. Derk Arts, MD, in 2012, Castor´s pro bono work during the pandemic has involved running World Health Organization´s ongoing Solidarity Trial on the platform, the world´s largest randomized trial, with more than 12,000 currently enrolled patients 2,145 investigators, and 553 sites across 30 countries currently participating, as well as 255 additional Covid-19 trials across 1,750 hospitals globally involving more than 125,500 participants and 160,000,000 data points. Standardization of data capture is key so that global data can be easily aggregated, accelerating the work of researchers developing critical medicines[7].

Needless to say, in large scale trials such as this, decreasing stakeholder burden is key to rapid patient enrolment, data entry and/or capture and then the use of that data. Patients, investigators, sites and researchers require digital continuity within one platform and system to ensure better experiences.

According to the New England Journal of Medicine, in seven months the Solidarity trial "answered the critically important question of possible mortality benefits of four highly touted regimens" and "informed the research agenda for the treatment of Covid-19," making a global impact thanks to its rapid scalability. It has been described by Lipset as "the ultimate manifestation of the shared economy[6,8]."

Arts describes the future that he´s trying to be a part of and help create, in which evidence-based medicine incorporates every single data point from every relevant patient or participant in a clinical trial.
"I believe that right now, if you look at the burden on patients that are participating in trials and how much of the data that they contribute affects other patients, 15 years down the road, it´s overwhelming.

> Multiple factors are due to play a role in shaping the future ecosystem of clinical trials, from converging technologies such as artificial intelligence and machine learning

"I would really like to be part of a future where we not only streamline clinical trials themselves and make them more patient-centric but we also maximize the impact of the data coming out of them by making it at least very easy to share data[8]."

The intellectual property and privacy challenges are addressable, Arts adds. "Generating synthetic data off the original data, provides an interesting perspective on circumventing some of those issues. Federated learning, as an example, has a lot of potential."

Harnessing such technology to transform collaborative capabilities promises to make medical research truly data driven. Machine readable endpoints for any clinical trial can be incorporated into a federated learning process, where ultimately the owner of the data, has the option to give access and where patients can opt in to do that.

"That would be the most beautiful outcome. It would require a lot of new steps, but the technology can support it," says Arts.

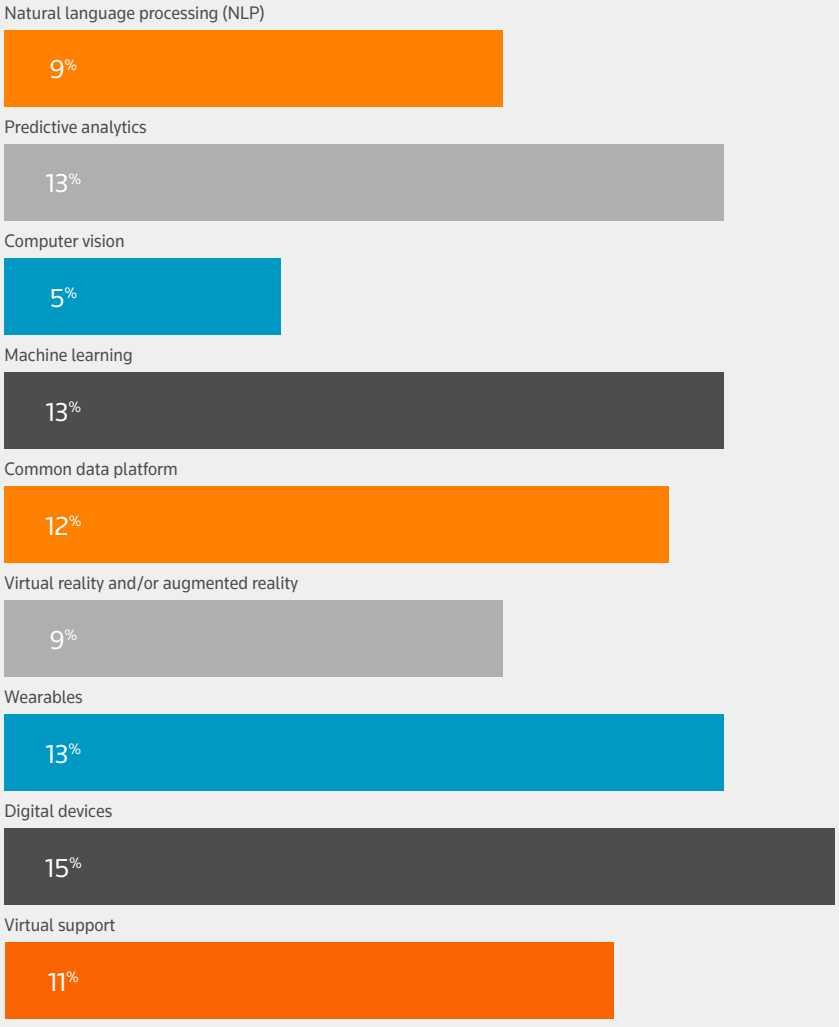
If the concept of data ownership were to shift towards data being "owned" fully by patients, bringing aspects of fair compensation into the picture, it could incentivize broader participation in trials and go some way to addressing the recruitment, accessibility and diversity issues that limit clinical trials today.

Jen Horonjeff, Founder and CEO of Savvy Cooperative, a data brokerage conceived to compensate patients for their data, tackles the controversial subject of how paying patients for a valuable commodity could introduce bias into clinical data: "It´s hard to argue that existing trials aren´t rife with bias in terms of individuals who are able to participate. If we don´t compensate for data, then we might be restricting access to populations that aren´t able to participate for economic reasons. Some people can participate out of altruism, but others can't[8]."

"Harnessing such technology to transform collaborative capabilities promises to make medical research truly data driven."

Dr. Derk Arts, MD, Castor

Q12. Which of the following technologies do you anticipate your organization using in clinical trials in 5 years' time?



How data sharing is evolving

The world is arguably undergoing rapid paradigm shifts triggered by the pandemic, including values, careers and whole economies. Organizations that are aligned with these shifts in economic paradigms and societal values, that excel at data sharing and collaboration, may have the 'edge' in the future. (5) Building a data-sharing strategy is about honoring the patients, building brand reputation, and can help with publication considerations, says Niamh McGuinness, Senior CTT Analyst at Privacy Analytics, an IQVIA company. Not only does data sharing lead to a greater number of citations but some influential journals such as the International Committee of Medical Journal Editors require contributors to publish their data-sharing plans.

According to Mesenbrink of Novartis: "Not all hypotheses can be answered solely within an industry sponsor´s data. Some hypotheses can only be addressed by patient data across trials from different sponsors[5]."

So, what about patients and privacy concerns? "Provided that adequate security safeguards were in place, most participants were willing to share their data for a wide range of uses" explains McGuinness, with over 82% of patients very or somewhat likely to share their data with scientists in for-profit companies.

For some organizations "patient-level data sharing has become routine," proclaims Jingyi Liu, Senior Director of Statistics, Data & Analytics at Eli Lilly and Company. "Data re-use greatly improves drug development efficiency, and data-sharing processes and platforms are well-established[5]."

By building an effective data sharing strategy the usefulness of data can live on instead of being shelved, says Laura Dodd, Senior Manager at Global Clinical Data Sharing for PRA Health Sciences, meaning "the medical community can spend money elsewhere." Dodd presents data that shows a median study cost of $19 million, and also draws attention to the fact that a great deal of time can be saved, potentially using anonymized data within a few months that could otherwise take years to obtain through further research[5].

The pandemic has also highlighted the potential for and value in a wider adoption of non-competitive collaboration within the industry, says Anindita Saha, Assistant Director of the Digital Health Center of Excellence at the US Food and Drug Administration also expresses a drive towards: "Let's try to bring people together in a more standardized way, with more open, pre-competitive aspects. We want to continue to engage in and work with the whole ecosystem through partnerships, collaborative communities, different activities, so we can all raise the ship together, promote health equity and continue to learn[8]."

Learning in this way from what has worked and from what hasn't when deploying digital health technologies, is important, says Saha.

> "We've learnt so many lessons from Covid, it would be a shame if we don't actually implement them, [such as] how we think about DCTs, remote data collection [and] tele-health."
>
> Anindita Saha, Assistant Director of the Digital Health Center of Excellence at the US Food and Drug Administration

"We need to keep going back to the patient, if we don't start there, we're going to keep exacerbating the same problems that we've had over and over again. We've learnt so many lessons from Covid, it would be a shame if we don't actually implement them, [such as] how we think about DCTs, remote data collection [and] tele-health.

The impact of converging technologies

A more efficient, collaborative future for trials will no doubt be shaped by the stacking of converging technologies like AI, ML and blockchain sharing platforms. This convergence will unlock new capabilities in the life sciences, says Dave Meyers, National Director of US Life Sciences at Microsoft.

"The things we will be able to do with genomics, artificial intelligence and machine learning is exciting. Looking at the rare disease scenario, there are interventions or flags that could be suggested by artificial intelligent algorithms with knowledge of symptoms, adverse events, phenotypes or other characteristics, that not every investigator would have at their fingertips.

"When we think about the increasingly routine nature of genomics and genetic analysis becoming low cost, accessible and practical, through the use of cloud computing, we see capabilities emerging that wouldn't have been possible a few years ago. They're increasing rapidly and will continue to accelerate in the coming months and years."

"We need to keep going back to the patient, if we don't start there, we're going to keep exacerbating the same problems that we've had over and over again."

Dave Meyers, National Director of US Life Sciences at Microsoft.

Q14. How is the evolving role of industry consortia impacting the end-to-end clinical trial process?

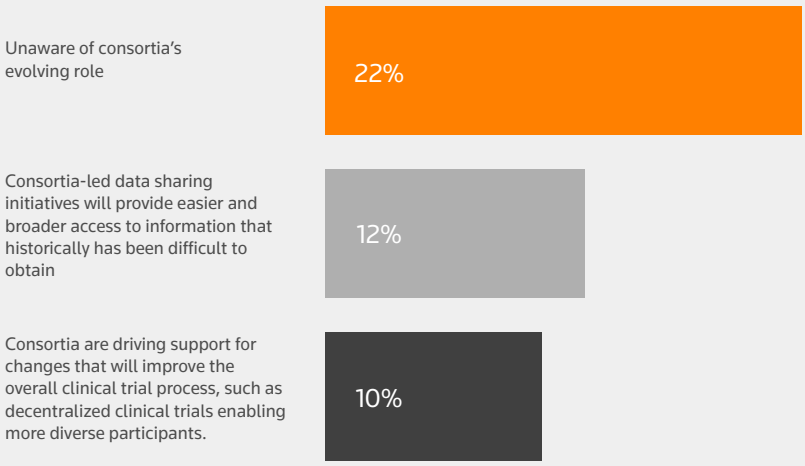


Figure 1. Reuters Events Pharma survey of 312 globally distributed industry professionals. Geographic responsibilities spread globally (28% global, 28% Europe, 20% North America and Mexico, 13% Asia-Pacific, 10% Other). Organization size ranging from 10,000 employees (54% of respondents) to less than 99 employees (14% of respondents) globally. (March 2022).

What´s expected in the next five years?

Data is being collected across all stages of development, from R&D through phase III and observational post-approval studies. Wearables and biosensors typically collect hundreds or thousands of data points per participant, as opposed to very few in traditional trials. The questions are: is the data being used efficiently, or as efficiently as it possibly could be, and how can technology play a role in increasing the efficiency of data use?

In solving this problem, the advent of cloud computing can't be underestimated. Investment in the remote monitoring space is growing rapidly. Meyers predicts "there will be huge investments both on the platform side and data management side, as well the devices and data collection. The computing power needed to efficiently use new data types is immense. This needs massive scale. Cloud computing together with AI are fundamentally important in this journey."

Lipset agrees: "We´re certainly seeing a lot of use of digital in study design and planning, and I think those investments will continue, using digital and data predictive analytics, as well as other means to optimize protocols, site selection, recruitment strategies, and finally the use of digital to drive end-to-end automation continues to be an area of investment."

Automation, according to Lipset, should deliver attractive ROI. Lipset notes the industry's attempts to pick the low-hanging fruit around decentralized trials including platforms that can support using mobile tools, video and electronic consent are well advanced. The next area for investment is likely to be in digitizing and modernizing endpoints.

Another big opportunity for the new digital tools to address is capturing insights from unstructured electronic health record data, Lipset adds. "How are we pulling that data and where is it going? Is it for the purpose of mapping into our Electronic Data Capture (EDC) system? Is it meant to sit adjacent to that system on its own? Are we using those data for purposes of accelerating the screening process [for trial entry], can we use it to reduce manual data entry?

"We could be using it for precision medicine purposes, to understand why one person responds differently from another, for long-term safety follow up. There´s a lot of good reasons to use that data, but data strategies are still a bit of a Wild West when it comes to how people are going about their work."

Participant recruitment, diversity, engagement, and retention

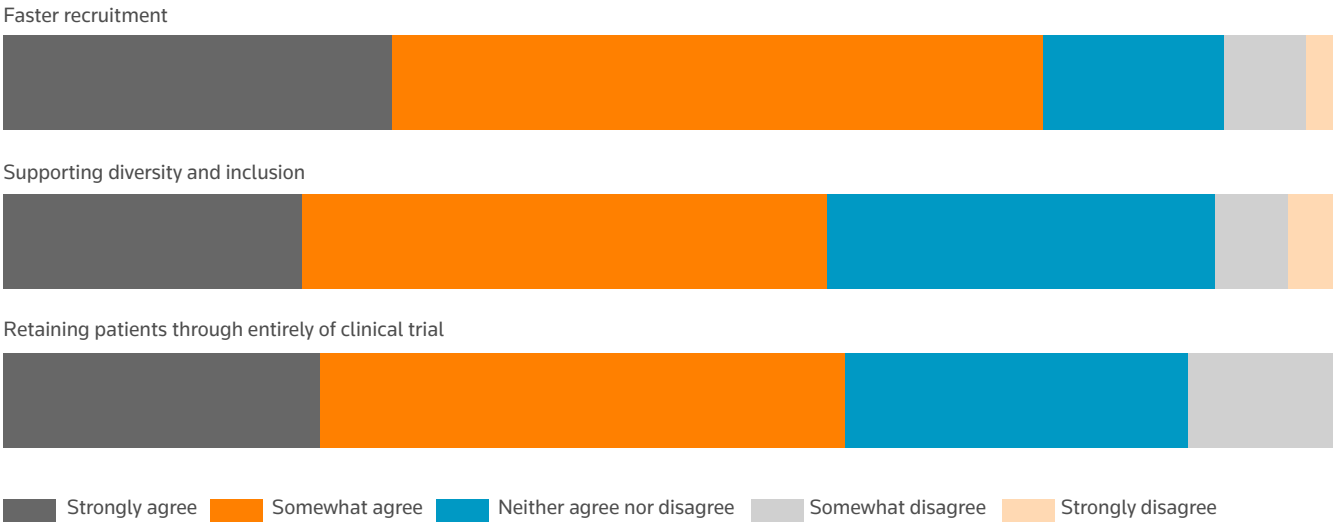
Digital tools have obvious applications for for making trials more convenient and pleasant for participants to enroll, consent and stay engaged. Not only could this potentially lead to higher enrollment by populations that are currently under-represented in most clinical research, but it could also help achieve better retention rates. The evolving clinical trial model has opportunities for some of the non-traditional players, such as CVS Health in partnership with Medable, and potentially other uses of retail, with potentially alternate venues for clinical trials.

Most survey respondents expect these tools to positively impact recruitment speed challenges with 76% of respondents agreeing or strongly agreeing that it will in fact be the top driver for improvement in this area. Similarly, more than half of respondents (61%) see technology as the top enabler for increasing diversity and inclusion in trials, and 63% believe technology will be the main driver behind future retention improvements.

"The computing power needed to efficiently use new data types is immense. This needs massive scale. Cloud computing, together with AI are fundamentally important in this journey."

Dave Meyers, National Director of US Life Sciences at Microsoft

Q13. Agree or disagree? Technology is the number 1 driver in positively impacting speed of recruitment, diversity and inclusion and in retaining patients through the entirety of the clinical trial.



Elizabeth Moench, founder of MediciGroup, now known as Accelerated Enrollment Solutions, a PPD company, which pioneered patient recruitment and retention techniques and which recruited at scale for the first clinical trial involving Apple watches, for GSK in 2016, when Apple's ResearchKit was launched, warns that despite their obvious appeal, the adoption of digital tools is moving faster than the ability to make sense of the data collected. "I think the desire to use the technology is still further ahead than the practical ability to get the data and integrate it into usable, insightful data sets. When it comes to recruitment, it all comes back to the data. There are always new ideas that all need to be tested before they get rolled out. Integrated data is key."

One under-explored use case for data analytics is finding and engaging with patients when they are most likely to participate in a trial.

"And it's all about timing, putting your offer of trial participation in front of people when they're actively taking steps to change their care. Predictive analytics could potentially be used to flag up when a patient is taking proactive steps towards changing their healthcare and may be more receptive to clinical trials," says Moench.

> "It's all about timing, putting your offer of trial participation in front of people when they're actively taking steps to change their care."
>
> Elizabeth Moench, founder of MediciGroup, now known as Accelerated Enrollment Solutions

Such individuals make motivated trial participants, she adds. "Patients who approach trials looking for an opportunity are more engaged. When we did a meta-analysis of 10 years of patient enrollment projects, we found that patients who play an active role in their own recruitment, who essentially approached us, had higher fidelity and dropped out far less. We found 40% improved retention rates."

Medici also found statistically significant improvements on participant retention due to remote screening and monitoring by nurses within their in-house call center.

New technology could also help ease recruitment issues by lessening restrictive exclusion criteria within clinical trial protocols. In the future, remote monitoring and predictive analytics of adverse events (AEs) could potentially make some comorbidities manageable without risk to the investigational product (IP), which could greatly speed up recruitment and reduce costs. This has considerable potential in elderly populations where comorbidities tend to stack up and could greatly speed up the search for treatments for age-related conditions like dementia.

But any adoption of novel technology must also factor in and work with immutable human needs and instincts, especially when it comes to making them feel the technology is not intrusive. "People are people, and their drivers don´t really change. If you want people to enroll in your trial, or accept a new technology, you have to get the psychology right," says Moench.

"I think there is a human instinct to not want to be watched and monitored all the time. In order to be successful, technology such as wearables or compliance devices used in clinical trials need to respect the human instinct for freedom and measure how the adoption of different technologies and solutions fare against expectations, using integrated data."

Moench is also adamant that making statistical assumptions be avoided at all costs. "It's a complex environment, technology can help a great deal but it's important we don´t assume that the effects will be exactly as we expected, the data needs to come in."

Nor should it be assumed that technology will automatically achieve certain desired outcomes, Moench adds. "You might expect remote access to clinical trials to increase diversity of participants. But you could also decrease enrolment in some populations, so this needs monitoring without assuming."

The Microsoft view

The life sciences industry is experiencing a rapid adoption of technology to improve productivity, drive medical advancements faster, and modernize design in R&D.

Harnessing the right tools is critical to transforming clinical trial strategy and execution, including smoothing product development, enhancing participant experience, revamping study management, and reducing costs.

From cloud platforms like Azure that centralize data for more accurate decision-making, to AI capabilities that boost patient engagement, every step of the R&D journey can be streamlined to speed up time-to-discovery and better meet clients' expectations.

Microsoft works with leading pharmaceutical and life sciences organizations to drive digital transformation, including innovating clinical trials, empowering R&D teams with unified datasets to ease data access and analysis, using machine learning to match patients with studies, and even using predictive behavior analytics to improve participant satisfaction. Our customers enjoy reduced time-to-insight, improved study outcomes, and enhanced collaboration between distributed teams to achieve advancements faster. Plus, digital tools drive compliance and strengthen patient security throughout the process.

Leading with trust and innovation in everything we do, Microsoft enables life sciences organizations to reduce cost of operations, support new business models, and enhance integration with partners to accelerate services to meet customer expectations. We do this by focusing on trust, security, and compliance, and scaled by the largest global partner ecosystem. To learn more, https://aka.ms/Pharmaceuticals

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Interviewees

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