



CLINICAL TRIALS

THE END OF 'ASSUMPTION HEALTH'? 6 WAYS CONSUMERIZATION IS CHANGING CLINICAL TRIALS

From Ambroise Paré's 1537 battlefield realization that egg yolk and turpentine worked better on wounds than oil, to the 2018 Nobel Prize-winning discovery of the revolutionary cancer treatment immunotherapy, clinical trials are the mechanism behind all global medical progress.

Yet they themselves are evolving as never before. The democratization of technology within healthcare has combined with changes in regulatory frameworks to create a new playing field. Trials now achieve more diversity and inclusion than ever previously anticipated - whilst unforeseen challenges have arisen and must be overcome.

The root cause of all this change actually lies outside the specific area of clinical trials. That's because the global healthcare industry in the 2020's is experiencing a revolution, based not on COVID-19, but on the concept of consumerization.

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The fact that we use the word 'consumerization' is interesting as arguably it's what we might expect already. After all, patients in most countries are used to paying, one way or the other, to try to maintain their health. We can think for example of private-sector insurance models, as in America, or indirectly funded state systems like those in Europe. In both cases the recipient is ultimately funding treatment. But, despite this, the life science & healthcare industry has seemed to take the view that healthcare patients are not really 'consumers' in the classic sense.

One patient interviewed by DHL's Senior Sector Expert, Dr Nana Bit-Avragim called this "assumption health" – a status quo in which the industry provides medicine and care, as it thinks best, and patients are assumed to be grateful and complicit. "Within this picture", Nana explains, "issues of health and medicine will always be mysterious to the lay person, who must instead rely upon experts' guidance. That's been the unspoken attitude."

Right across the world, however, the empowering nature of information is causing that relationship to change. "Cynical stories about 'Dr Google' are becoming a bit of a cliché", says Thomas Ellmann, Vice President of Clinical Trials Logistics for DHL. "It's because everyone in the sector knows patients will increasingly self-diagnose and develop opinions to bring to the conversation. They want a two-way relationship. And this will affect the players present in the healthcare market, not just our behaviours."

This last point is very telling with Silicon Valley companies, from outside the medical industry, either planning or making entries into the field. Apple's revised Health phone app now enables users to track not only doses of medication, but also to research and price match them. This information will not be used passively, we can be sure. For example, featured in one Apple forum user's comments on the app's latest functionality:

"I found out about a couple interactions (between my meds)... my doctor never told me about them. I have some questions for him now."

Since 2020, Forbes reports a 3800% growth in telemedicine, showing patients that many traditional doctor appointments don't need to be physically face-to-face. Already, the ability of technology to replace the traditional hospital with a 'home-spital' has been widely reported on. On-demand pharma companies now exist. Besides telemedical consultations and asynchronous chat, there are tech startups in home care[, direct-to-consumer lab testing, wearable diagnostic/monitoring devices and digital health record management.

In fact, DataArt claims, "it's estimated the addressable market for the consumerization of healthcare was \$600 billion in 2019 and will increase at 5.5 CAGR through 2025".

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Dr. Nana Bit-Avragim
Senior Sector Expert
DHL Supply Chain

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Thomas Ellmann
Vice President Clinical Trials
DHL CSI

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SURELY CLINICAL TRIALS ARE SPECIAL?

Throughout all this, the main focus is obviously on ongoing treatment, with proven medicines and techniques. But clinical trials won't be immune to this trend towards partnership between patient and provider. Or will they?

Whilst drug-based interventional DCTs (decentralised clinical trials) jumped to 77% of one survey of activity between the second halves of 2019 and 2020, this was in contrast to previously sluggish growth and partly in response to COVID-19 'force majeure'. Post pandemic, anecdotal evidence suggests that some people in clinical trials quietly believe a lot of the broader trend towards patient empowerment will pass them by.

Ultimately, some will say, traditional methodologies are a known quantity. In contrast, a Tufts CSDD study found that, while 55 percent of sampled clinical trials had moved to 'virtual' since the Spring of 2020, 60 percent of investigative sites "reported having no prior experience with remote processes and solutions before the pandemic." So, it's a big learning curve for many.

There are other possible reasons for slow adoption, too. In face-to-face visits, participants can build relationships, with investigators and coordinators, which increase their commitment to the trial. Operators may fear the loss of this. And, regarding efficacy, there isn't a long history of evidence, to fall back on when signing off methodologies, with DCT.



YESTERDAY IS NOT AN OPTION

All those objections are understandable - but ultimately, it's false to suggest there is a 'business as usual' option.

As already mentioned above, developments like new FDA regulations and the 2021 G7 Therapeutics and Vaccines Clinical Trials Charter increasingly mandate a broader, more representative sample within trials. Patient needs are increasingly in focus within that.

Dr Matthias Roos, Pharma Sector Lead for fast-growing digital platform provider Climedo, interacts with a lot of sponsors and CROs, getting a good overview of the sector as it considers change. Asked about genuine patient-centricity, he sees a mixed picture.

Such remarks on patient benefit suggest parts of the trials industry possibly has a mindset adjustment to make. It's not really their fault, however.

"Quite correctly, legislators and medical scientists talk a lot about patient safety and trial compliance, when proposing change," says Thomas Ellmann. "But at the same time patients themselves have a different set of 'pain points' to account for. So, what true consumerization, as opposed to decentralization, implies is a philosophy of wanting patient's needs and motives to be first and foremost, when designing a methodology."

Perhaps sponsors might be forgiven for thinking this sounds like a lot of 'new work.' And it is. But the benefits will be game changing.

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I'd say there are two kinds of player segments: segment one is an experienced player, segment two is new joiners. The experienced player already uses digital questionnaires and so on. They are aware of the pitfalls but see the benefits. The new joiners are usually those with more traditional trial's setups. Perhaps they have used digital but not to make the experience of the patient itself more beneficial.

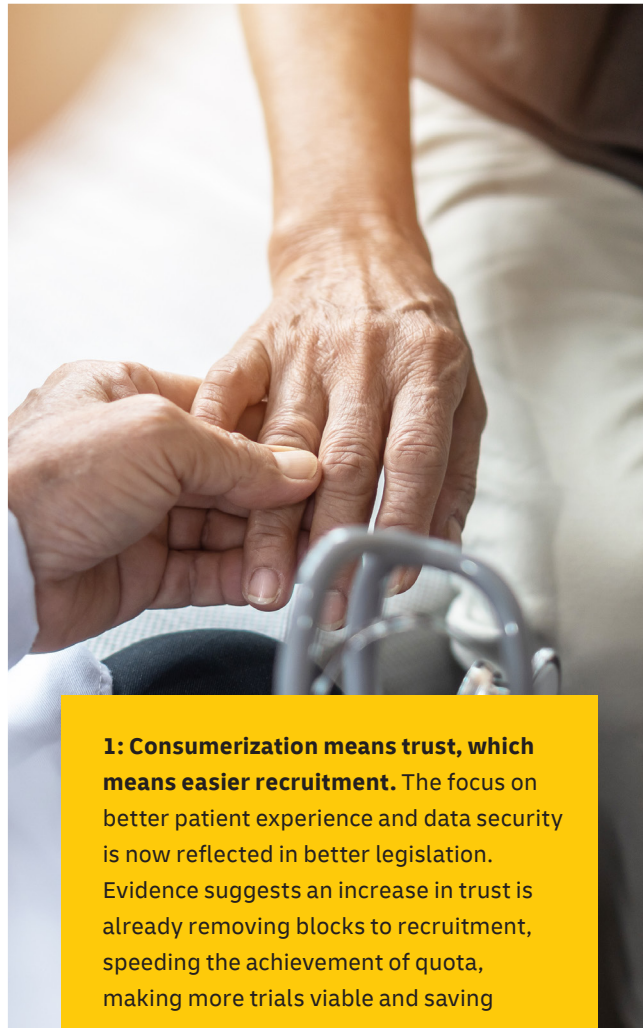


Dr Matthias Roos
Pharma Sector Lead
Climedo

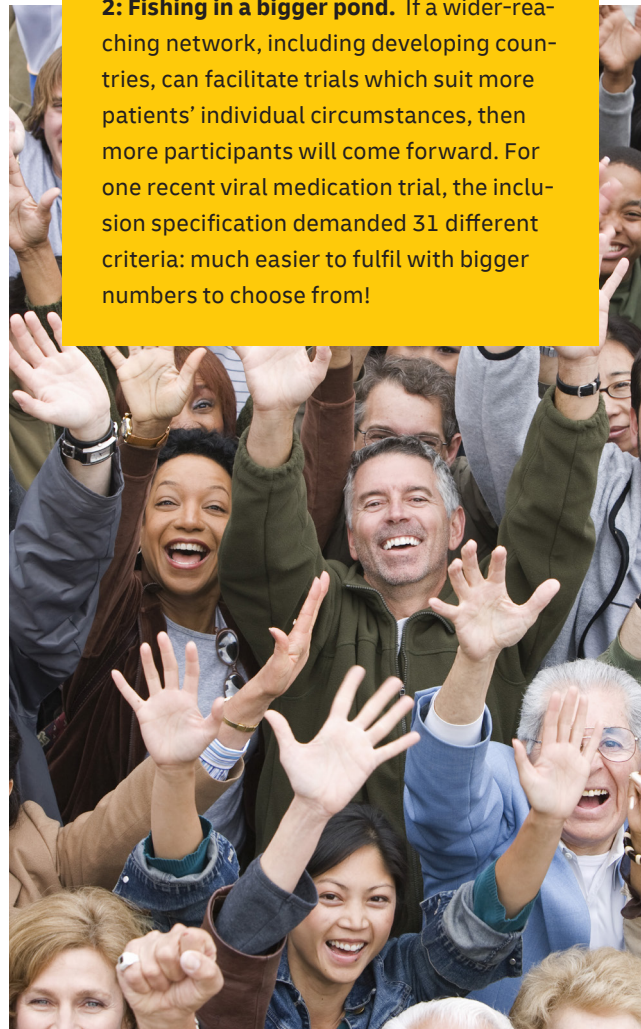
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SIX WAYS CLINICAL TRIALS WILL BETTER EVOLVE

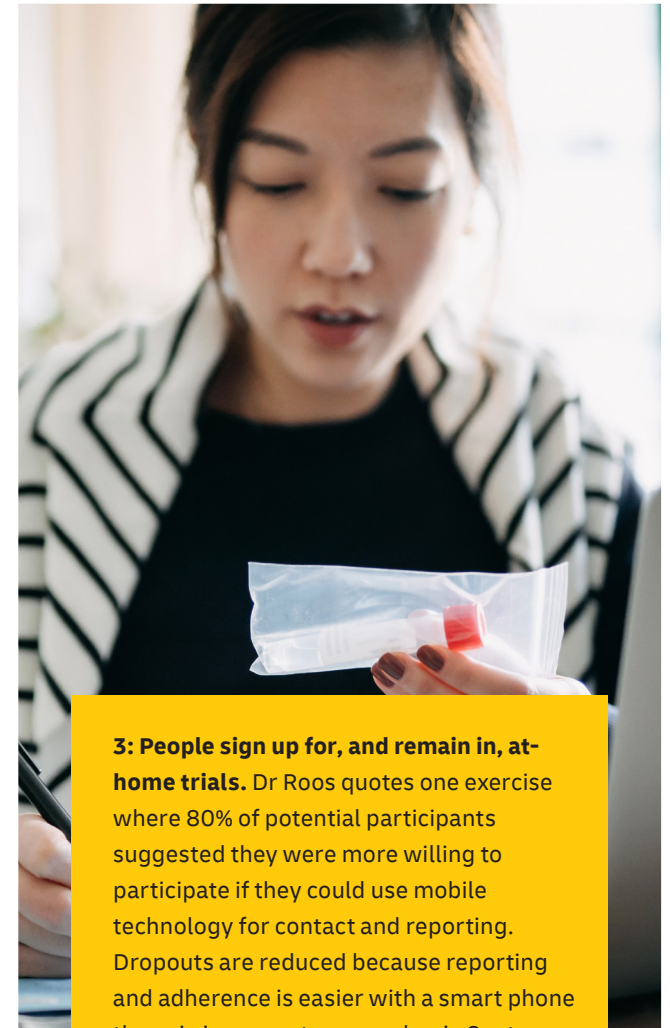
As this article title suggests, successfully abandoning 'assumption health' for the partnership model means welcoming, not saying goodbye to, a 'golden age' of trials. Instead of seeing consumerization as a response to competitive threats from Silicon Valley, or to legislation; sponsors should be eagerly pursuing change. Here are six big reasons why.



1: Consumerization means trust, which means easier recruitment. The focus on better patient experience and data security is now reflected in better legislation. Evidence suggests an increase in trust is already removing blocks to recruitment, speeding the achievement of quota, making more trials viable and saving money.



2: Fishing in a bigger pond. If a wider-reaching network, including developing countries, can facilitate trials which suit more patients' individual circumstances, then more participants will come forward. For one recent viral medication trial, the inclusion specification demanded 31 different criteria: much easier to fulfil with bigger numbers to choose from!



3: People sign up for, and remain in, at-home trials. Dr Roos quotes one exercise where 80% of potential participants suggested they were more willing to participate if they could use mobile technology for contact and reporting. Dropouts are reduced because reporting and adherence is easier with a smart phone than via journeys to an academic Center.

4: Always-on data beats the old model.

Data errors have undermined thousands of trials in the past. The combination of remote reporting, AI and even wearable technology, as well as keeping patients' workloads down, eliminates the manual mistakes of the past.



5: The Future Is Individual. The future of medicine lies in sophisticated treatments, mRNA vaccines, cell and gene therapies. Solving the unsolved problems of modern medicine will thus increasingly mean individualised treatments. In that context, the ability to conduct clinical trials on a very personalised level, with both diagnostics and treatment choice being data-driven, will open up new possibilities .



6: A New Opportunity To Excel!

Lastly, perhaps controversially, those sponsors and CROs that make their clinical trials more consumerized will outperform less able competitors. Matthias Roos makes this point:

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“It feels similar to the e-commerce sector. One day Amazon introduced next day delivery for free – nowadays, many people are demanding it as standard. I think it will be similar with clinical trials and patient-centricity”.



Dr Matthias Roos
Pharma Sector Lead
Climedo

“Think maybe of a patient with osteoarthritis – there could be any number of trials for which that individual would be useful; yet they can pick one only. Such a patient might be confronted with many hours of physically difficult and painful travel in order to present at a test site, where the alternative is remaining largely comfortable at home using digital reporting tech. Which trial do you think they'll choose?”

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HELPING TO MAKE IT HAPPEN

All this, therefore, is available to be gained by forward-looking sponsors.

However, there is one element that needs to be factored in: the supply chain can still make or break a trial. If deliveries or collections fail, or cold chain disruption occurs, patient outcomes, clinical endpoints and licensing approvals are all on the line.

“We always bear in mind that at the end of every logistics chain there is a patient. When those patients are participating in trials, but away from traditional sites, the chains need to be cleverer and more responsive. This is not an impossible fete and we’re showing that we can do this”, says Claudia Roa, Life Science & Healthcare President for DHL.

There is certainly plenty of evidence that sponsors needn’t see logistics as an obstacle to new practice. Perhaps some of the challenges of decentralization may even have ready-made solutions?

“Certainly – we are able to use our Same Day online web portal to, for example facilitate IMP delivery to a patient’s home, or home pickup of biological samples to deliver to a lab, without any loss of confidentiality,” Roa continues. “We’ve also had experience of developing single ordering points for trials with multiple clinic locations – each obviously serving numerous patients. Within this, it’s already perfectly possible to achieve delivery windows as small as 2 hours from order placement.”

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Such capacity supported a study by Medable, into dry age-related macular degeneration. The worldwide sample included thousands of underrepresented patients, who were recruited and pre-screened from their homes. Data capture was conducted via mobile apps. Meanwhile, partnering with DHL, procedures described above for at-home genetic test shipments and pick-ups were successfully incorporated. This methodology made a more diverse and patient-friendly test possible.

Elsewhere, DHL clients using DCT have recognised the issues around ‘dynamic patient recruitment’ – put simply, participants drop out and need replacing. One solution has been to develop centralised stocking locations across the geographic spread of trials – letting materials relating to participation be rapidly deployed to new individuals.

With careful organisation, and use of compliant secondary packaging, such sites can also supply participants with an ‘all you need’ package of trials materials, upon enrolment. Thus, separate items like syringes, storage containers and technical equipment don’t confuse patients with multiple packages and the recipient gets to ‘take on board’ everything in one go, reducing anxiety.

Claudia Roa
President
Life Sciences & Healthcare Sector
DHL Customer Solutions & Innovation



IN CONCLUSION

There is always a lot of detail in clinical trials but there is a simple 'elevator pitch' we should feel good about.

The pandemic has focused attention on long-term concerns about the composition of clinical trials, so, at the very least we have new regulatory standards to achieve; this can't be done easily with traditional methodologies, yet can be if we adopt a more consumerized model; doing that might seem like a lot of new behaviors, but consumerization is not only unavoidable, it will demonstrate a long list of benefits, not least cost savings and a better rate of trial success; and, the logistics learning curve is already being overcome.

As is so often the case, the future turns out to be better than the PAST.

THE FUTURE OF CLINICAL TRIALS

Watch an exceptional line-up of clinical trials industry experts discuss what the industry will look like in the near and longer future and what impact will be on supply chains

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