Teckro: A Strategic Tool for Sustainability, Diversity, Employee and Site Engagement, and Smarter Trials

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Introduction

Now that travel's a possibility again, I've enjoyed a couple of in-person business meetings in Bangalore, India, as well as industry conferences, including the recent ACRP 2022 meeting in Orlando, Florida.

Some topics were little changed since before the pandemic – such as the need to advance diversity and social determinants of health, widening our aperture and giving everyone access to clinical research as a care option (CRAACO). Others have evolved based on our experiences during the pandemic. Some of the newer topics gaining traction are those centered in environmental, social and governance (ESG) initiatives. These are increasingly being tackled by pharma companies and CROs through corporate environmental and sustainability efforts, diversity, equity and inclusion (DEI), with corporate governance being addressed through stakeholder engagement initiatives.

Interestingly enough, on April 22, 2022, I shared the podium with Malia Lewin, global head of strategy at Teckro, to discuss how Teckro is supporting companies in their quest for better ESG strategies. The Teckro platform – a mobile, digital clinical trial hub that has been used to date at 30,000 study sites in more than 4,700 cities and 70 countries – can help reduce environmental impact with a digital alternative.[1] Here, I'll take a look at the platform's positive impacts on sustainability, diversity, governance (site engagement), and on the industry's quest of designing smarter trials.

Sustainability

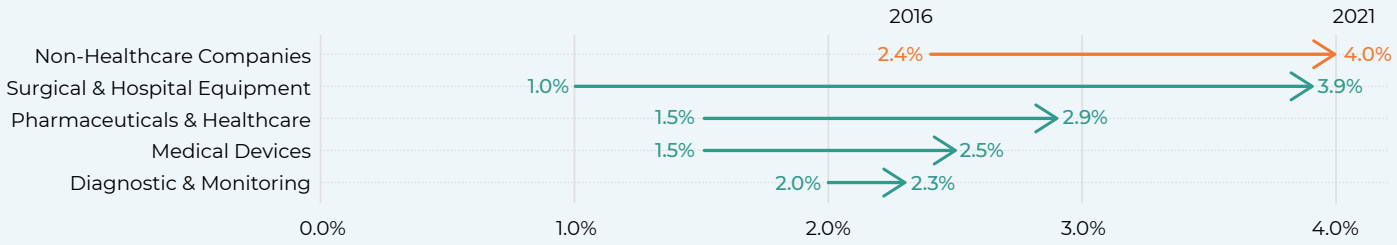
For many industries, digital advances have positively impacted carbon footprints. Yet, the clinical trials industry lags behind, still being driven mainly by manual and paper-based processes that impact sustainability. These include printing and shipping vast quantities of paper documents and supplies in support of multi-year global clinical trials.

While sustainability may not be a term that is immediately associated with clinical trials, Malia Lewin and I considered on a podcast on World Earth Day that Teckro is a positive tool for impacting sustainability efforts. Teckro's platform streamlines communications, leading to less CRA travel, less need for printing paper documents, lower shipping costs, more trial efficiency via protocol automation, and a greener approach overall.[2]

This fits within broader global efforts to improve sustainability. Climate change remains a major focus – fueled in part by high-profile activists such as Greta Thunberg. At last month's World Economic Forum in Davos, Switzerland, a third of main stage panel discussions were related to global warming.[3] And the United Nations continues to work towards sustainable development goal #3, to ensure healthy lives and promote well-being for everyone – of all ages.[4]

The ESG framework that defines and manages sustainability risks is very much a pharma concern that shows no sign of abatement.[5] There has been a positive trend of ESG mentions in healthcare company filings over the years (Figure 1).[6] The share of sentences that mention ESG in healthcare company filings rose from 1.4% in 2016 to 2.5% in 2021, according to GlobalData.[7] As FiercePharma wrote recently, "traditionally referred to as corporate social responsibility or sustainability, the newer ESG moniker has become a rallying point for millennial fund investors and younger employees who want to work at companies that do good in the world."[8]

Figure 1: ESG mentions in healthcare are rising but still trail non-healthcare companies [9]



Source: GlobalData

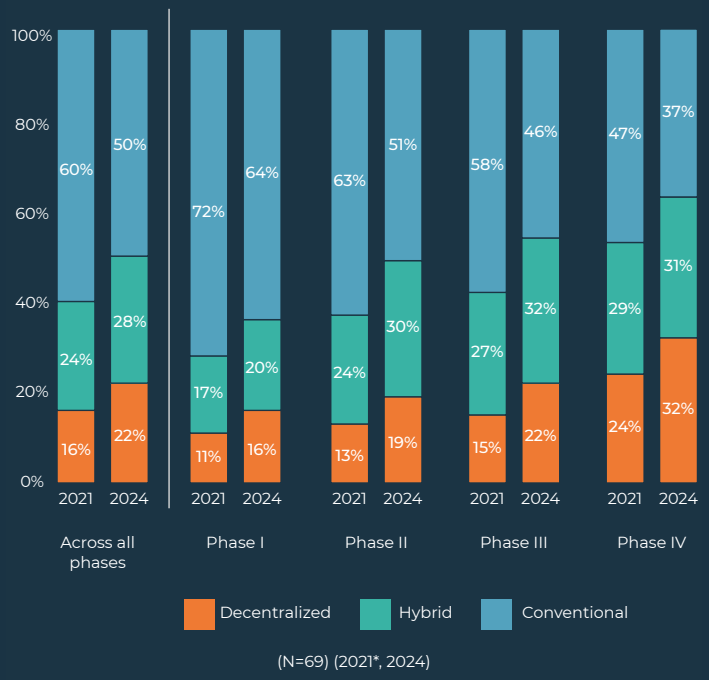
This increasing interest in ESG is also reflected in industry rankings, including a recent one by Alva's ESG Intelligence, which uses 26 SASB[10] sustainability business categories to classify millions of pieces of business-related content, examined 20 pharma companies from January 1 through April 30, 2021.[11] The top three were Boehringer Ingelheim, earning kudos for a switch to wind power at a manufacturing plant; Biogen, recognized for work to improve diversity in clinical trials and Astellas, with diversity efforts including an interest in ideas addressing health inequalities through its C3 Prize innovation challenge.[12] Biogen was also given kudos for a commitment to boost diversity by 30% in U.S. manager positions and above, and increase numbers of women directors by 30% around the world by the end of 2021.

DCTs as a step forward in sustainability

Decentralized clinical trials (DCTs), which advanced sharply during the COVID-19 pandemic, offer multiple sustainability benefits. These include reduction in travel by patients and clinical research personnel alike, and reduced need for paper records, due to reliance on new tools and technologies – such as paper surveys replaced by electronic clinical outcome assessments (eCOAs), paper informed consent forms by electronic ones, and data collection increasingly collected from wearables rather than bringing the patient into the clinic.

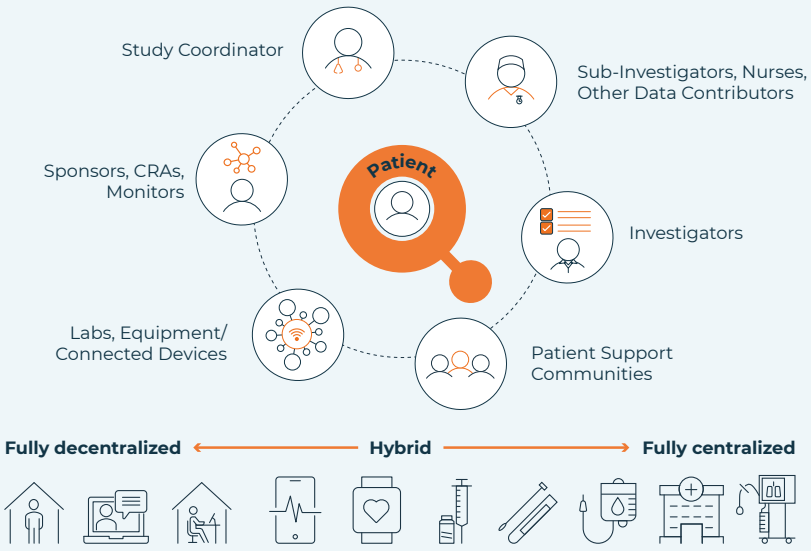
As we might expect from these benefits to sites' carbon footprints, the future for hybrid and DCTs looks bright based on survey results and EY-Parthenon analysis.[13] A poll of 69 sponsor and CRO decision-makers found that half of biopharmaceutical clinical trials expected to be either hybrid or completely decentralized by 2024.[14] Underlying elements supporting DCTs have been anchored to time savings and a shift toward patient-centric approaches. Survey respondents said the clinical trial landscape is currently divided as follows: 60% conventional trials, 24% hybrid trials and 16% decentralized trials (Figure 2). But by 2024, survey respondents predict that 28% of trials will be hybrid and 22% decentralized.[15]

Figure 2: Breakdown of clinical trial approaches [16]



Teckro supports these efforts, advancing both DCTs and sustainability (Figure 3),[17] by enabling all stakeholders efforts at the point of care, regardless of location, service provider, home health staff or research site. The benefits of quality and efficiency with Teckro extend to all trial formats, wherever and whenever enablement of key stakeholders is required. As sponsor companies and CROs alike work to bring the clinical trial to the patient, Teckro's positive impact on sustainability is a feather in the cap of companies looking to lighten their environmental impact.

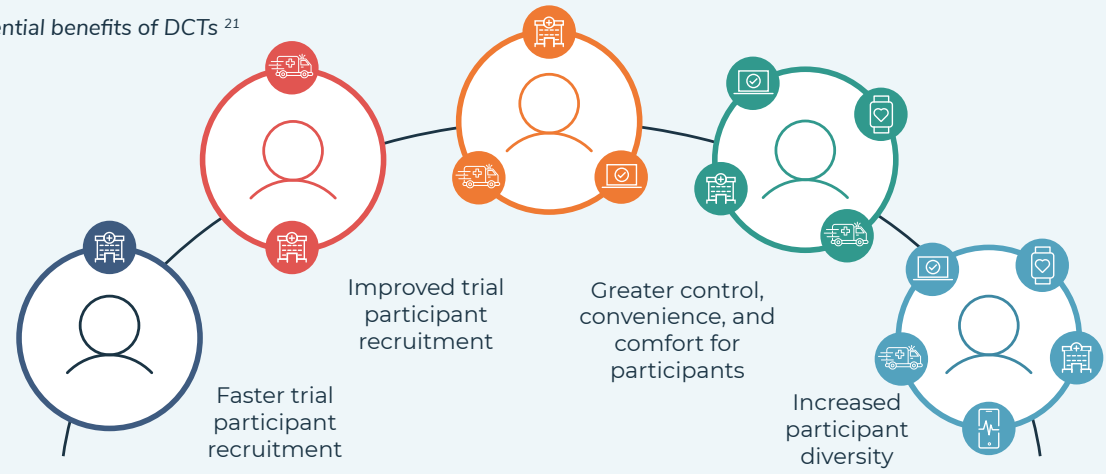
Figure 3: Teckro connects all stakeholders, supports all trial formats



Diversity

The "social" element of companies' environmental, social and governance (ESG) frameworks can also support increased diversity in clinical trials. Lack of diversity in clinical trial populations still features often in the headlines. DCTs can help here, improving inclusivity by reaching geographically distant or isolated patients, and enabling participation of individuals with mobility, cognitive and economic challenges (Figure 4).[18] In a recent clinical diversity initiative Pfizer announced that it would work with the trial site network Headlands Research to launch new research sites in diversely populated areas.[19, 20]

Figure 4: Potential benefits of DCTs [21]



Source: Clinical Trials Transformation Initiative

The US Food and Drug Administration (FDA) continues to explore ways to encourage participation of underrepresented populations in clinical trials through guidances (including the April 2022 publication of guidance on diversity plans for trial participants [22]), tools and innovative trial design.[23]

A recent National Academies report cites an urgent need to recruit more diverse trial participants.[24, 25] The report says that persistent lack of diversity in trials is a critical issue that harms populations that are left out of pivotal medical studies and the entire biomedical research enterprise. National Academies says lack of representation:

- costs hundreds of billions of dollars;
- may hinder innovation and new discoveries;
- may compound the low accrual rates that cause many trials to fail;
- may lead to lack of access to effective medical interventions;
- may undermine trust of the clinical research enterprise and the medical establishment;
- and compounds health disparities.

By supporting implementation of DCTs, Teckro helps advance inclusion of more diverse patient populations. Teckro harnesses technology to support less experienced site staff – providing training materials on-demand, offering real-time access to study-related advice, and making the protocol accessible from any digital device. Real-time answers mean better decisions for diverse patient enrollment, a tool to support research-naïve sites or newer investigators. Users have commented that Teckro is like having a "virtual coach" nearby offering help.

Teckro can help address the findings of a pilot study that qualifications of site staff may influence the overall protocol deviation rates, with qualified nursing staff potentially having fewer deviations than individuals without nursing qualifications.[26]

> **"Wearable tech is praised for expanding underserved communities' access to clinical trials, but may not detect heart rates for people with darker skin.** [27]

> **"While women and minorities are getting more attention around cardiovascular disease, drug trials are still not addressing their physiological differences.** [28]

> **"Not all physicians recognize that women have different symptoms for heart disease than men, and women have made up just 20-30% of relevant drug and device trials.** [29]

Governance (site engagement)

Governance and site engagement are also critical issues. Better communication flow with sites – supported by Teckro – leads to better governance and higher quality data. This also drives better decision-making; less friction between sites, sponsors and CROs; ready access to knowledgeable resources; greater job satisfaction; fewer errors; easier onboarding of new site staff members; and potentially less turnover.

Teckro can support successful DEI and CRAACO initiatives by empowering inexperienced sites and personnel. The platform can support new principle investigators (PIs), potentially reducing the share of investigators who leave clinical research after carrying out a single trial – known as 'one-and-done.' This trend is already showing a decrease, according to an analysis by the Tufts CSDD. This found that the proportion of PIs that belonged to the "one-and-done." decreased from 70% in 2015 to 66% in 2020.[30] Teckro can help drive the continuation of this trend.

Teckro is also a useful tool for home health nurses, enabling them to use their smartphones to access electronic copies of the protocol, informed consent and other documents to support DCTs. Teckro allows home health nurses to search for information or obtain real-time answers from study personnel while with the patient. The platform also supports data security, by providing access on the nurse's phone at the patient's location rather than on a laptop in a car.

The conversation about supporting sites dates as far back as 2017 when the Clinical Trials Transformation Initiative (CTTI) issued recommendations for strengthening the investigator site community.[31] Key recommendations aim to reduce turnover, enhance efficiency, and ultimately support faster trials with more engaged patients and researchers (sidebar).

What Sites Say

Site Engagement Translates into Site Satisfaction with Teckro

8 in 10 PIs Satisfied with Teckro

7 in 10 Regular Users Satisfied with Teckro

8 in 10 PIs & CRAs Agree Teckro offers faster access to study document and staff

8 in 10 PIs Agree Teckro is useful in their day-to-day role

7 in 10 PIs Found the answers they were looking for using Teckro

Source: A site satisfaction survey of 137 participants and 5 qualitative interviews conducted by Teckro

CTTI Recommendations for Strengthening the Investigator Site Community [32]

I. Recommendations for Developing Site-Based Research Infrastructure & Staff

Recommendations for Investigative Sites

1. Hire and retain well-trained, experienced research coordinators and other essential staff.
2. Provide continuous training for research staff.
3. Guide clinical research practice at the site with standard operating procedures (SOPs) and systems.

Recommendations for Sponsors, CROs, and Health Systems/Private Practices

1. Recognize principal investigators, co-investigators, and research coordinators as key contributors to product development.
2. Provide opportunities for investigators and site staff to remain engaged in between trials.

II. Recommendations for Optimizing Trial Execution and Conduct

Recommendations for Sponsors

1. Create enrollable study protocols and ensure effective recruitment planning.
2. Follow FDA safety reporting requirements.

Recommendations for Investigative Sites and Health Systems/Private Practices

1. Determine whether the study protocol is suitable for your site.
2. Manage recruitment effectively.

III. Recommendations for Site Budget and Contract Negotiations

Recommendations for Investigative Sites

1. Review the study protocol and create cost assessments.
2. Ensure that staff understand key contract components.
3. Plan for and address delayed/outstanding payments.
4. Manage site cash flow concerns.

Recommendations for Sponsors and CROs

1. Use master agreements whenever possible.
2. Foster transparency about fair market value (FMV) determination.

IV: Recommendations for Investigators Interested in Conducting Additional Studies

1. Make use of investigator/trial matchmaking systems.
2. Contact sponsors and CROs directly.

Designing Smarter Trials

Racial disparities in health and healthcare are not new. They have been observed and quantified across many major diseases as far back as two decades ago, with a vast report titled Unequal Treatment.[33,34] This pointed out that even after socioeconomic factors had been taken into account, "race and ethnicity remain significant predictors of the quality of healthcare received." As STAT notes in a February 2022 article, "Why has so little changed? …That grim truth has been made startlingly clear by both the pandemic and by statistics that show Black Americans continue to die up to five years earlier than those who are white." The article concludes that there are many contributing factors.

Yet, despite the fact that funding for health equity has increased, the needle still doesn't seem to have moved. Human-centered design processes were developed to address this gap. They start by seeking to understand the feelings, needs and perspectives of people who will use the design, and end with purpose-built solutions to meet these needs. Human-centered design is widely used in many industries today, but its use is lagging in healthcare.

The FDA is pursuing various efforts to encourage voluntary patient engagement in clinical studies, based on the belief that patient input into study design may help address challenges in medical device development.[35] While the FDA acknowledges that patient engagement may be beneficial across the total product lifecycle, its January 2022 guidance focuses on the applications of patient engagement in the design and conduct of medical device clinical studies.[36]

Many sponsors are working to engage patients in trial design, with initiatives in diseases such as ulcerative colitis (Pfizer[37]), and immuno-oncology (BMS[38]). Recent papers describe efforts to engage patients in the design of studies related to pediatric asthma,[39] bladder cancer[40] and kidney disease,[41] with a meta-analysis of 26 studies finding that patient and public involvement interventions are likely to improve enrollment of trial participants.[42]

The communication capabilities of Teckro can be used both to keep research staff informed and to survey them to get feedback on possible clinical study design. By giving physician researchers and site staff more of a voice in protocol development, this is likely to be more realistic from the start, resulting in fewer amendments, less wasted time chasing unrealistic patient populations, and sites more vested in the research/drugs coming to market because they are helping to shape the protocol designs.

Additionally, Teckro can also drive communication with PIs outside of the protocol in the medical affairs arena, for example capturing insights from PIs about standard care/treatment pathways or suitability of inclusion/exclusion criteria. This insight can then be used to support better design of clinical trials.

Here are some considerations for incorporating patients' experiences into health equity endeavors:

- Recognize that diversifying the workforce does not replace the need for harnessing the expertise of underrepresented patient populations.
- Realize that providers may not have a complete or unbiased understanding of the experience and unmet needs of Black or other underrepresented patient populations.
- Consider hiring consultants or building in-house expertise in qualitative research, behavioral science, and human-centered design.
- Appreciate that people who have been marginalized have untapped yet essential knowledge that healthcare lacks to address health disparities .
- Solicit the feedback of these patients who have been marginalized to inform, shape, and validate health equity solutions – and offer compensation for this valuable input.
- Augment quantitative research with empathetic, in-depth interviews to better understand the clinical experiences of underserved patients.
- Consider using Teckro to support efforts to solicit feedback on trial design from clinical trialists, their staff and their patients.

Conclusion

As a silver lining to the COVID-19 pandemic, DCTs are now firmly part of the clinical research landscape. This is having the knock-on effect of advancing the ESG efforts of clinical research stakeholders from pharma companies, to CROs and clinical sites. Building on this momentum, Teckro can be part of the solution for improving clinical trial diversity and healthcare equity. Teckro is delivering advances in sustainability, driving reductions in the need for travel, paper print-outs and shipping. By improving communications, this unique platform is empowering inexperienced sites and personnel, while amplifying site engagement and informing patient-centric trial design. These features support the evolution of clinical trials and the delivery of both DEI and CRAACO – to the potential benefit of the entire clinical trial enterprise.

About JTH Consulting

JTH Consulting & Associates (JTH) is a boutique advisory and consulting services company that partners with companies around the world and across the lifesciences marketplace. JTH partners with companies of all stages and sizes to align operations and commercial segments with the strategy, insights, structure and processes to win in the market.

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