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Sustainability in Clinical Trials: Purposeful Digitalization is Key

Its integration is opening up more opportunities for sustainable study practices.

In 2023, clinical development productivity rose the highest it has been since 2018, primarily due to an increase in clinical trial success rates in Phase I and III studies and related regulatory review across diseases areas.[1] This growth in clinical R&D is essential to ensuring there are more viable treatment options for patients in need globally. Along with the industrywide goal to advance healthcare with quickness and high quality, R&D stakeholders also aim to design and drive forward sustainable clinical trial practices for patients.

While some fundamental drug development practices are necessary and clinical trial sponsors cannot shift away from them, these companies and their R&D partners, including contract research organizations (CROs), are committed to minimizing the environmental impact of their programs. And as in other aspects of R&D, these stakeholders are exploring new and innovative ways to make a noticeable change in sustainable practices for their trials.

Digitized R&D

The end-to-end digitalization of clinical trials is growing by the day, providing many takeaways on how technology-enabled solutions are helping to accelerate drug development with increased efficiencies and quality. With this digital transformation, it is worth exploring how integration of advanced technologies is creating more opportunities for sustainable trial practices.

Remote data monitoring (reducing travel and conserving resources)

During COVID-19, there was an uptake of decentralized trial (DCT) and hybrid trial designs. We learned a great deal about how intuitive cloud-based DCT platforms and other technologies helped effectively coordinate research and workflows to support patient, site, and study team communication and capture study activity (e.g., visit coordination and remote data monitoring) without putting patient data at risk. This also reduced site visits for patients and clinical research associates (CRAs).

As trials continue to move toward centralized monitoring for site support, CRAs can monitor data remotely while reducing travel to and from sites and conserving resources (e.g., CRA time). In some cases, travel to sites can be reduced by up to 30%. In traditional ways of working, CRAs may physically be onsite, but most of their time sometimes goes to time-consuming tasks, including manual data input from multiple sources and correcting electronic case report forms, which can leave gaps in data oversight. With centralized monitoring, sponsors can leverage targeted analytics using artificial intelligence (AI)/machine learning modeling to mine incoming data remotely and consistently gauge risk-mitigation to course-correct quicker while also being environmentally sensitive.

As data capture processes go digital with more seamless flow from electronic medical records to electronic data capture, and as the use of connected devices and wearable technologies in clinical trials grows, site teams, CRAs, and study teams will have holistic views of data for oversight at any time. This tech-enabled data flow reduces the reliance on manually inputting data and paper-based documentation and review activities.

Site and patient experience digitalization (conserving resources)

Beyond collecting data directly from patients, there are multiple clinical trial activities that traditionally were paper-based for patients that are now available in various digitized formats. Not only are the digital solutions noted ahead designed to reduce patient burdens to trial participation and improve experiences, but they also reduce paper production and related waste:

- Clinical trial materials critical to patient enrollment are available electronically, such as electronic consent forms.
- Sites can now share digital trial kits with patients that include QR codes for more information about the trial instead of paper brochures, posters, and other printed materials.
- Investigator site files and trial master files are also available in electronic forms.
- Furthermore, investigational products can be managed remotely through data integration and mobile technologies.

For every digitalization practice the industry adopts, e-waste will also be required to be sustainable, including electronic hardware.

Supply chain optimization (reducing waste)

Trial sponsors have a multitude of partners and vendors within their clinical trial supply chain framework. As such, individual partners, such as CROs, need to ensure their own supplier networks are committed to reducing emissions from shipments and removing excess waste from investigational products that support R&D.

CROs can ensure optimized supply chain strategies within trials they oversee by integrating clinical supply chain management as a key function within study teams and by closely collaborating to better mitigate risk and logistical challenges that may increase unnecessary wastage of investigational product. This is especially critical for cell and gene therapy and other novel design trials, where manufacturing, supply chain, and logistics can be intricate and lead to treatment wastage if not planned for and executed efficiently.

With the oversight of an experienced clinical supply chain manager, integration of an interactive response technology (IRT) allows study teams to manage supply in real-time and monitor progress every step of the way to avoid drug wastage due to sitting product and address unforeseen challenges in the process quickly. When IRTs seamlessly integrate with vendor systems and to patient data via data management platforms, the fuller team has end-to-end visibility and does not have to rely on sites and clinical teams, which may use manual trackers to monitor supply.

Third-party guidance

As with many other aspects of clinical trial planning and operations, it is important to look outside of the four walls of a company to ensure these activities are conducted with high quality, safety in mind and improved outcomes. For example, when it comes to trial data processing, sponsors aim to follow the Clinical Data Interchange Standards Consortium standards,or for DCT elements, they will need to comply with the International Council for Harmonization's Good Clinical Practice E6 (Revision 2) guidelines[2] In the same vein, sustainability in R&D needs industry standards to guide tangible progress, help quantify the environmental impact of clinical trial design, and delivery to develop sustainability-specific targets and to provide ways to simply be better without compromising trial quality.

The Sustainable Healthcare Coalition is an industry organization working with healthcare industry stakeholders to identify opportunities to enhance sustainability in patient care and share best practices. As the focus on sustainable clinical trials expands and additional insights are gathered, it may be beneficial for trial sponsors and CROs to closely follow this coalition and others for guidance.

Where can sustainable clinical trials go?

It will be interesting to see how additional use of AI and automation in clinical trials will help to enhance sustainability in future trial design and monitoring. Can trials go even more remote to reduce environmental impact without compromising data quality and patient safety? For example, AI-driven solutions may eventually provide sponsors and CROs more proactive oversight and may allow clinical monitoring to target the most critical data.

The importance of improving patients' lives through critical drug development goes hand-in-hand with optimizing clinical trials to be more sustainable and creating a healthier environment for those very individuals. As such, the industry is dedicated to further evaluating sustainable clinical trial best practices and which key approaches are the most impactful. With more insights under the industry's collective belt, there will be more knowledge to share to refine sustainable trial practices for the better.

References

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