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Mini Review

Sustainability in Clinical Research: Perspectives in Building Environmentally Responsible and Patient-Centered Clinical Trials

Eva Troja*

*Profarma Sh.a., Tirana, Albania

***Correspondence:** Eva Troja, Profarma Sh.a., Tirana, Albania, E-mail: eva_troja@yahoo.com; DOI: 10.1042/JCTCS.9.1.0060

Abstract

Clinical research is fundamental to advancing healthcare, yet its environmental footprint has received limited attention until recently. Clinical trials generate substantial greenhouse gas emissions through participant travel, site operations, laboratory testing, supply chains, energy consumption, and research waste. As healthcare systems increasingly recognize climate change as a major public health challenge, being sustainable has become a crucial part of clinical research. Recent initiatives promote greener trial designs through digital technologies, decentralized and hybrid clinical trials, sustainable procurement, optimized logistics, and improved reporting of environmental outcomes. These strategies offer opportunities to reduce carbon emissions while still making sure the trials are scientifically sound, safety for patients, and produce reliable data. Nevertheless, challenges remain, including the absence of standardized sustainability metrics, regulatory guidance, and global reporting frameworks.

In this paper, a summary perspective on environmental impact of clinical trials, discusses current strategies for improving sustainability, and highlights future directions for integrating environmental stewardship into clinical research.

Key words: Sustainability, Clinical trials, Carbon footprint, Green research, Decentralized, Digital health

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Introduction

Conducting clinical trials is crucial for evaluating the safety and efficacy of new therapies. Nevertheless, the ecological impact of research activities has been traditionally overlooked. Extensive travel by participants and investigators is necessary for large multicenter trials, along with frequent shipment of biological samples and investigational products, energy-intensive research facilities, and substantial use of disposable materials. Together, these factors contribute to greenhouse gas emissions and resource consumption. Recent analyses indicate that individual clinical trials can produce substantial carbon emissions based on their scale and complexity, which has driven efforts to embed sustainability principles into research design and governance **[1].**

As climate change increasingly affects health systems, environmentally sustainable clinical research is becoming both an ethical responsibility and an operational priority.

Sources of environmental impact

The environmental footprint of clinical research arises from several interconnected activities:

- Participant and investigator travel
- Energy consumption at research sites

- Laboratory analyses and biobanking
- Shipping of investigational medicinal products and biological specimens
- Single-use plastics and medical waste
- Data storage and digital infrastructure
- Manufacturing and distribution of trial materials

Travel and logistics are among the largest contributors to trial-related carbon emissions, particularly in multinational studies with frequent monitoring visits **[2].**

Sustainable trial design

Sustainability should be considered during protocol development rather than after trial initiation. The practical validity of this proactive approach is clearly illustrated by the comparative carbon footprint analysis of the global CRASH-1 and CRASH-2 trials, which evaluated treatments for traumatic bleeding. Researchers conducted a retrospective carbon footprint analysis of both trials, demonstrating how embedding simplicity directly into the protocol phase dramatically shrinks environmental impact. Despite CRASH-2 enrolling twice as many patients across more countries, the simplified protocol reduced the trial's total carbon footprint by nearly one-third compared to CRASH-1 **[3].**

Decentralized and hybrid clinical trials

Telemedicine, electronic informed consent, wearable devices, home nursing visits, and remote monitoring reduce unnecessary travel while improving participant convenience. Hybrid trial models combine remote assessments with essential in-person visits, lowering emissions without compromising data quality **[1].**

Digital transformation

Electronic case report forms, remote site monitoring, cloud-based document management, and virtual investigator meetings substantially reduce paper consumption and travel. These technologies also improve operational efficiency and facilitate faster data management **[4-7].**

Risk-based monitoring

Modern risk-based monitoring strategies focus onsite visits where they provide the greatest value while replacing routine monitoring with centralized data review. This reduces travel-related emissions and operational costs.

Sustainable procurement and supply chains

Clinical trials rely on complex global supply chains. Sustainable procurement strategies include:

- Environmentally responsible sourcing of trial materials
- Reduction of unnecessary packaging
- Local manufacturing where feasible
- Efficient shipment planning
- Reusable equipment when appropriate

Sponsors increasingly recognize procurement decisions as important determinants of trial-related carbon emissions **[1, 8-12].**

Measuring environmental performance

Unlike financial or clinical outcomes, standardized environmental indicators for clinical trials remain underdeveloped. Potential sustainability metrics include:

- Carbon emissions per participant
- Participant travel distance
- Energy consumption
- Medical waste generated

- Paper utilization
- Percentage of remote visits
- Sustainable procurement indicators

Recent reviews emphasize the need for validated methods to quantify the carbon footprint of clinical trials and enable comparisons across studies **[13-17].**

Ethical and regulatory considerations

Environmental sustainability is increasingly viewed as an ethical consideration alongside participant safety and scientific validity. Some scholars argue that research ethics committees should evaluate sustainability during protocol review, recognizing responsible resource use as part of ethical clinical research **[4].**

International organizations are also beginning to develop guidance on integrating climate considerations into trial design and oversight. In 2026, the World Health Organization published recommendations addressing climate change mitigation and adaptation throughout the clinical trial lifecycle **[1].**

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Challenges

Despite growing momentum, several barriers remain:

- Lack of universally accepted sustainability standards
- Limited reporting of environmental outcomes in published trials
- Variable regulatory requirements across countries
- Digital inequalities affecting decentralized research
- Balancing sustainability with participant safety and scientific rigor

Recent analyses have shown that environmental sustainability considerations are rarely reported in randomized clinical trial publications, highlighting the need for improved reporting standards **[1, 18-20].**

Figure 1 presents a conceptual framework illustrating how sustainable clinical trial practices contribute to both environmental responsibility and patient-centered research. The figure demonstrates that integrating decentralized and hybrid trial designs, digital technologies (e.g., electronic informed consent, electronic patient-reported outcomes, electronic Trial Master Files), remote monitoring, and optimized logistics can reduce travel, paper consumption, energy use, and resource utilization. These sustainable practices not only decrease the environmental footprint of clinical research but also improve patient accessibility, convenience, recruitment, retention, and overall trial efficiency. Together, these interconnected strategies support the development of high-quality clinical trials that align scientific excellence with environmental sustainability and patient-centered care.

Figure 1. Conceptual figure illustrating the relationship between sustainable clinical trial practices and their environmental benefits.

Real-world applications of sustainable clinical trials

The transition toward sustainable clinical research is increasingly supported by practical implementation of decentralized and digital trial methodologies. Through literature, strategies such as telemedicine, electronic informed consent, remote monitoring, electronic patient-reported outcomes, cloud-based data management, and risk-based monitoring have consistently demonstrated their potential to reduce travel requirements, paper consumption, energy use, and operational waste. These approaches not only contribute to lowering the environmental footprint of clinical trials but also improve participant convenience, accessibility, and study efficiency. Lessons learned during the COVID-19 pandemic further accelerated the adoption of these innovative practices, highlighting that sustainability and patient-centeredness are complementary objectives rather than competing priorities. Collectively, these examples demonstrate that integrating environmental considerations into trial design and conduct can enhance both research quality and healthcare sustainability **[Table 1]**.

Example	Sustainable strategy	Reported benefits	Key reference (s)
Decentralized clinical trials (DCTs)	Telemedicine, remote monitoring, e-Consent, home nursing	Reduced participant travel, lower carbon emissions, improved recruitment and retention	**21-23**
Hybrid clinical trial designs	Combination of virtual and on-site visits	Reduced travel burden while maintaining protocol compliance	**21, 22**
Electronic clinical outcome assessments (eCOA/ePRO)	Digital-patient-reported outcomes replacing paper questionnaires	Reduced paper consumption, fewer transcription errors, improved patient convenience	**24**
Risk-based and centralized monitoring	Remote data review and targeted site visits	Reduced monitor travel, lower operational costs, improved efficiency	**25, 21**
Electronic Trial Master Files (eTMF) and cloud-based data management	Digital document management	Reduced paper use, printing, storage, and shipping requirements	**25**
Green logistics	Direct-to-patient drug shipment and optimized supply chains	Reduced transportation emissions and material waste	**26, 27**

Table 1: Examples of sustainable clinical trial strategies, their implementation, reported environmental and operational benefits.

Future perspectives

To establish a climate-resilient and environmentally sustainable clinical research ecosystem, the global research community must transition from fragmented, voluntary initiatives toward an institutionalized, structural framework. Future clinical research should integrate sustainability into every stage of the trial lifecycle. Priority areas include developing standardized carbon accounting tools, incorporating environmental outcomes into trial reporting guidelines, expanding decentralized and hybrid trial models where appropriate, encouraging sustainable procurement practices, and embedding sustainability within research ethics and funding decisions. Collaboration among investigators, regulators, ethics committees, patients, industry partners and sponsors will be essential to ensure that environmentally responsible practices complement rather than compromise scientific quality and participant protection.

Future advancements in this domain can be organized into four strategic, interdependent pillars that collectively safeguard scientific integrity while systematically reducing carbon and material expenditures.

Pillar 1: Regulatory and policy shifts

A fundamental requirement for long-term decarbonization is the integration of environmental stewardship into the governance of clinical research. Future iterations of International Council for Harmonization (ICH) Good Clinical Practice (GCP) guidelines must evolve to explicitly validate decentralized, paperless, and low-carbon operational procedures as standard acceptable practices rather than exceptions.

Furthermore, regulatory bodies and public registries (e.g., ClinicalTrials.gov, EudraCT) should consider mandating prospective environmental impact disclosures within trial protocols. Finally, Institutional Review Boards (IRBs) and Research Ethics Committees (RECs), which traditionally evaluate only human subject protections, must be empowered to include basic trial eco-efficiency into their institutional review workflows, correcting the widespread lack of formal institutional oversight.

Pillar 2: Harmonized standardization and metrics

The current inability to cross-examine trial footprints stems from severe methodology fragmentation. The widespread adoption and enforcement of specialized reporting extensions, specifically the upcoming SPIRIT-ICE (Standard Protocol Items: Recommendations for Interventional Trials International Compliance for Environment) and CONSORT-ICE (Consolidated Standards of Reporting Trials International Compliance for Environment) frameworks will represent a major milestone. Beyond reporting, the industry requires open-access, validated Life Cycle Assessment (LCA) calculators specifically calibrated for clinical trial operations. These tools will enable protocol authors to model carbon variables, such as patient travel, site energy, and drug supply lines during the design phase, shifting environmental accounting from a retrospective exercise to a predictive science.

Pillar 3: Technological integration and infrastructure

Digital transformation remains an operational backbone for sustainable trials, yet its future relies heavily on systemic interoperability and green infrastructure. Future protocols must leverage unified digital architectures that bridge Electronic Health Records (EHR) with decentralized clinical trial (DCT) systems to eliminate redundant data collection loops and reduce administrative energy. Concurrently, pharmaceutical sponsors must deploy machine learning and predictive analytics within the clinical supply chain. By accurately forecasting localized recruitment rates, interactive response technologies (IRT) can drive Just-in-Time (JIT) manufacturing, drastically cutting down the historical over-manufacturing buffer and subsequent biohazardous waste. Crucially, as clinical operations become increasingly digitized, the research enterprise must mandate that cloud data hosting and data management vendors utilize exclusively carbon-neutral, renewably powered data infrastructure.

Pillar 4: Institutional and cultural evolution

Ultimately, operationalizing these sustainable pathways requires a profound cultural shift across the global research workforce. Academic medical centers, contract research organizations (CROs), and pharmaceutical sponsors must invest heavily in capacity building, providing clinical trial managers and principal investigators with formal training in environmental sustainability metrics. To prevent the implementation of green protocols from worsening existing clinical trial inequities, global health coalitions must proactively fund digital and healthcare infrastructure in low- and middle-income countries (LMICs). Closing this digital divide ensures that decentralized, low-carbon trials do not inadvertently alienate diverse or resource-limited patient populations, thereby preserving the generalizability and ethical foundation of global clinical research.

Conclusion

The integration of environmental sustainability into clinical trials is no longer an optional ethical consideration but a core component of high-quality clinical research. By minimizing unnecessary travel, embracing digital technologies, streamlining supply chains, and implementing standardized environmental metrics, eco-friendly clinical trials at the protocol stage prevent the carbon lock-in associated with traditional, site-heavy paradigms. While systemic barriers ranging from regulatory fragmentation to digital inequities continue to obstruct immediate progress, transitioning toward the four strategic pillars of regulatory adaptation, unified metrics, technological interoperability, and global capacity building offers a viable roadmap forward. By embedding carbon reduction directly into the fabric of trial design, the clinical research enterprise can meaningfully minimize its environmental footprint without compromising scientific rigor, data validity, or participant safety.

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