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Sustainability Accounting and its Impact on Sustainability Assurance Practice in Clinical Research: An Analytical Report

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Abstract

Decentralized and virtual clinical trials are expanding to improve patient access but create new sustainability challenges: emissions from drug shipments and patient travel, e-waste from home devices, and energy use from digital platforms. Regulators, sponsors, and patients now demand transparency on environmental and social impacts of trials, including carbon footprint, participant diversity, waste management, and ethical supply chains. Yet healthcare ESG disclosures remain largely voluntary and unaudited, raising risks of greenwashing. This report examines how sustainability accounting through ISSB IFRS S1 and S2 has shifted clinical trial ESG disclosures from narrative reporting to material data requiring rigorous assurance. The IAASB's ISSA 5000, approved in September 2024, provides the first global baseline for sustainability assurance. Its features framework neutrality, scalability, professional skepticism, and support for both limited and reasonable assurance make it directly applicable to clinical research. Challenges include independence threats, ceremonial decoupling, data availability under HIPAA and GDPR, and competence gaps requiring Good Clinical Practice expertise alongside environmental science. Opportunities include enhanced trial transparency, operational efficiency, and stakeholder trust. ISSA 5000 elevates sustainability assurance to the rigor of GCP audits. For sponsors, Contract Research Organizations, and hospitals, integrating ISSA 5000 into clinical governance is now a strategic imperative to meet the Corporate Sustainability Reporting Directive, validate "green trial" claims, and maintain public trust.

Key Words: Sustainability accounting, Clinical trials, Decentralized trials, Healthcare ESG, Double materiality

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Introduction and research problem

Healthcare accounts for approximately 4.4% of global greenhouse gas emissions, with clinical trials contributing through patient travel, cold-chain logistics, single-use plastics and energy-intensive data centers. A single large Phase 3 trial can generate up to 3,000 metric tonnes of carbon dioxide equivalent, and the sector overall emits an estimated 100 million tonnes annually-comparable to the national footprint of Belgium. Concurrently, a widening range of stakeholders demands transparency on trial sustainability: carbon per patient enrolled, participant diversity relative to disease prevalence, waste management practices, and the ethical integrity of supply chains.

"Sustainability accounting" emerged to measure these non-financial impacts in a systematic, comparable manner. "Sustainability assurance" developed subsequently to enhance the credibility of reported information. However, assurance remains nascent in healthcare, often limited to unverified corporate social responsibility statements that lack independent scrutiny **[1].** The research problem addressed by this report is: What is the impact of sustainability accounting on sustainability assurance practices within clinical research organizations and hospitals under the newly issued ISSA 5000?

Conceptual framework

Sustainability accounting in healthcare

Grounded in stakeholder theory and legitimacy theory, sustainability accounting adopts the concept of Double Materiality. Impact materiality assesses how trials affect the environment and society-for example, the carbon emissions generated by patient travel to clinical sites or the social consequences of excluding minority populations from a life-saving drug trial. Financial materiality, conversely, assesses how environmental, social, and governance factors affect trial costs, patient recruitment success, and access to capital. A trial that fails to meet diversity targets may face regulatory delays from the FDA or European Medicines Agency, directly impacting its financial viability and timeline to market **[2].**

The International Sustainability Standards Board issued IFRS S1 and S2 in 2023, institutionalizing this shift. IFRS S1 requires disclosure of all sustainability risks affecting enterprise value. IFRS S2 requires climate-specific disclosures, directly relevant to trial Scope 3 emissions from patient travel, site monitoring visits, and cold-chain logistics. These standards are interoperable with the Global Reporting Initiative and the Task Force on Climate-related Financial Disclosures. Complementary frameworks include the Sustainability Accounting Standards Board Biotechnology and Pharmaceuticals Standard, which provides industry-specific metrics on participant safety and access to medicines, and the AA1000 Assurance Standard, which is principles-based and emphasizes inclusivity and stakeholder impact.

Sustainability assurance for clinical research

The International Auditing and Assurance Standards Board defines assurance as the independent enhancement of user confidence in reported information. Sustainability assurance for clinical trials is therefore an independent assessment of whether a trial's ESG disclosures are prepared according to agreed criteria, free from material misstatement.

ISSA 5000, approved in September 2024, is the first comprehensive global baseline for sustainability assurance. For clinical research, its relevance lies in four interconnected features. Framework neutrality means it works equally well with GRI, ISSB, the NHS Net Zero standard, or any internally developed criteria. Scalability allows assurance to be applied to a single metric such as "carbon dioxide equivalent emissions per Phase III trial" - or to a full CRO sustainability report **[3,4]**. Professional skepticism permits clinical research experts, environmental scientists, and health equity specialists to join assurance teams alongside traditional auditors. Support for both limited and reasonable assurance allows the depth of work to be proportionate to user needs and the materiality of the metric in question.

Ethical requirements are provided by the International Ethics Standards for Sustainability Assurance, effective December 2026. IESSA mandates independence, professional skepticism and appropriate competence, ensuring that sustainability assurance is conducted with the same ethical rigor as financial audits.

Results and discussion

Impact of sustainability accounting on assurance in clinical trials

Three major shifts emerge from the integration of sustainability accounting into clinical research. First, the shift from form to substance. Before ISSB standards, sponsors might claim "green trials" or "diverse recruitment" without verifiable data. Such narrative disclosures were difficult to challenge but also provided little credible information to stakeholders. Under IFRS S1 and S2, assurance practitioners must evaluate how emissions, diversity metrics, and waste management affect trial risks, costs, and stakeholder trust. This aligns sustainability assurance with the objectives of Good Clinical Practice audits, which focus on patient safety and data integrity **[5].**

Second, standardisation through ISSA 5000 ends the fragmented, inconsistent approaches that previously characterised sustainability assurance. A CRO operating across multiple countries can now assure a metric such as "diversity of participants relative to disease burden" using consistent principles globally. The International Organization of Securities Commissions endorsed ISSA 5000 in November 2024, confirming regulatory acceptance across major capital markets. Research by Bentley-Goode and colleagues found that assurance provided by professional accounting firms is associated with higher quality sustainability reports and more frequent restatements of prior errors - a finding directly applicable to clinical trial ESG data, where initial errors in carbon accounting or diversity reporting may require correction.

Third, sustainability assurance is being integrated into clinical governance. As noted in Deloitte's analysis of sustainability trends, entities must apply the same financial reporting discipline to ESG data as they do to financial statements **[6].** For CROs and hospital research units, this means that audit and quality committees are now responsible for the reliability of sustainability data, alongside their traditional responsibilities for patient safety and data integrity.

Challenges in assuring healthcare ESG data

Despite the promise of ISSA 5000, five significant challenges persist in the clinical research context. The independence dilemma is acute. Approximately 78% of Fortune 500 firms use their financial auditor to provide sustainability assurance. For a CRO, if the same firm audits the financial statements and also assures claims of a "carbon-neutral trial," self-review threats arise under IESSA. The assurance firm may be reluctant to identify errors in data that management has already approved for financial reporting.

Ceremonial decoupling remains a risk. Research by Belal and colleagues found that entities may procure sustainability assurance primarily as a legitimizing gesture, without genuine commitment to improving ESG performance. In clinical trials, these risks producing "assured" diversity reports that show improved metrics on paper but do not reflect meaningful changes in patient recruitment practices **[7].**

Data availability and privacy constraints present unique challenges. Patient travel distances, site energy consumption, and supply chain emissions are rarely collected systematically. While ISSA 5000 permits the use of estimates where direct data is unavailable, it requires full disclosure of estimation methods and assumptions. More fundamentally, patient privacy laws such as HIPAA in the United States and GDPR in Europe limit access to raw patient data during assurance procedures.

The competence gap is particularly wide. Effective sustainability assurance for trials requires not only traditional auditing skills but also knowledge of GCP, environmental life cycle assessment, health equity measurement, and regulatory frameworks. Weak stakeholder engagement undermines double materiality, as many trial ESG reports are prepared without meaningful dialogue with patient communities or environmental advocacy groups **[8-9].**

Opportunities: transparency, efficiency and trust

Despite these challenges, significant opportunities emerge. Enhancing transparency is the most immediate benefit. Credible assurance reduces information asymmetry between trial sponsors and stakeholders, including regulators, investors, and patient communities.

Operational efficiency often follows from systematic measurement. When sponsors begin measuring emissions and waste with an eye to assurance, they frequently identify inefficiencies. Decentralized and virtual trials can cut travel-related emissions by 40 to 60% while simultaneously improving patient recruitment and retention **[10].** Research by LaRoche and colleagues identified that pharmaceutical manufacturing contributes approximately 50% of trial emissions, patient travel contributes 10%, and site monitoring travel contributes another 10%. Each category can be targeted for reduction.

Mitigating greenwashing is perhaps the most urgent opportunity. The withdrawn EU Green Claims Directive highlighted that approximately 53% of environmental claims made by companies were vague, misleading, or unsupported by evidence. Robust assurance under ISSA 5000 provides the antidote.

Regulatory alignment is increasingly important. The EU CSRD mandates sustainability assurance for large sponsors operating in Europe, and ISSA 5000 provides the baseline standard **[11].** Finally, stakeholder trust is enhanced when diversity and community benefit claims are independently verified.

Conclusion

Three main conclusions emerge. First, ISSB/IFRS S1/S2 have made clinical trial ESG data financially and operationally material. Sustainability accounting has shifted assurance from the verification of narrative statements to rigorous, risk-based procedures. Second, ISSA 5000 provides rigor equivalent to GCP audits for sustainability data, with specific provisions for estimates and forward-looking information **[12].** Third, the challenges of independence, data privacy, and multidisciplinary competence are addressable through careful engagement design and investment in privacy-preserving data systems.

Recommendations

For regulators and funders, ISSA 5000 should be referenced in grant requirements, with limited assurance required for large publicly funded trials. Proportionate provisions should be adopted for small and medium-sized biotech's.

For sponsors and CROs, sustainability assurance should be integrated into existing quality management systems. A practical pathway is to begin with limited assurance on two or three metrics and progress to reasonable assurance over two to three years. Investment in data capture systems will reduce reliance on estimates.

For assurance providers, building multidisciplinary teams is essential, including financial auditors, clinical operations experts, environmental scientists, and health equity specialists. IESSA independence requirements must be applied strictly.

For researchers, empirical studies are needed on the impact of sustainability assurance on trial enrollment, cost of capital, and patient trust. In clinical research, where public trust is paramount, ISSA 5000 will distinguish genuine commitment from symbolic claims.

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