Environmental sustainability in clinical research

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Greenhouse gases have a significant impact on the global climate. The healthcare sector is one of the main sources of CO_2 emissions. Globally, it represents the fifth largest source. Clinical research is an integral part of this sector; it drives innovation, but also places an additional burden on the environment. Therefore, efforts to minimize the carbon footprint are also permeating the methodology and design of clinical trials as well as clinical research in general.
Digitization and decentralization of clinical trials can help to reduce the environmental burden. However, these benefits remain largely hypothetical now due to limited supporting data. In order to develop more sustainable clinical trial methodologies, it is necessary to quantify emissions in clinical research more precisely and identify key areas for reducing emissions in clinical research.
This article aims to raise awareness of sustainable clinical research and present relevant initiatives and activities.

Key words: sustainability, clinical trials, healthcare, clinical research, education.

Environmentální udržitelnost v klinickém výzkumu

Skleníkové plyny zásadně ovlivňují globální klima. Sektor zdravotní péče představuje jeden z významných zdrojů emisí CO_2, v celosvětovém měřítku se řadí na páté místo. Klinický výzkum je jeho nedílnou součástí; přináší inovace, ale i další environmentální zátěž. Snaha minimalizovat uhlíkovou stopu proto prostupuje i do metodologie a designu klinických studií a klinického výzkumu jako celku.
Prvky jako digitalizace a decentralizace klinických studií mohou přispět ke snižování environmentální zátěže. Stále jde ale spíše o předpoklad podložený omezenými daty. K dosažení udržitelnějších metodik je třeba cílenější kvantifikace a identifikace klíčových oblastí pro redukci emisí v klinickém výzkumu.
Článek si klade za cíl zviditelnit problematiku udržitelného klinického výzkumu, představit iniciativy a aktivity v této oblasti.

Klíčová slova: udržitelnost, klinické studie, zdravotnictví, klinický výzkum, vzdělávání.

Does sustainable healthcare matter?

The global healthcare sector has emerged as a significant contributor to anthropogenic climate change. Current estimates indicate that it represents 1–5% of the total impact on climate change, producing approximately 2.0–2.6 billion tons of CO_2 emissions globally per year corresponding to 4.4–5% of the global greenhouse gas emissions. Thus, the healthcare sector ranks fifth among the largest CO_2 producers. The production of CO_2 emissions contributes to climate change and health issues or deaths related to climate change (often expressed in disability-adjusted life years – DALYs). Treating them imposes monetary costs for the healthcare system and simultaneously generates additional CO_2 emissions. This creates a downward spiral and is precisely why healthcare represents

DECLARATIONS:

Declaration of originality:
The manuscript is original and has not been published or submitted elsewhere.

Ethical principles compliance:
The authors attest that their study was approved by the local Ethical Committee and is in compliance with human studies and animal welfare regulations of the authors' institutions as well as with the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th WMA General Assembly in Helsinki, Finland, in June 1964, with subsequent amendments, as well as with the ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals, updated in December 2018, including patient consent where appropriate.

Conflict of interest and financial disclosures:
None.

Funding/Support:
Supported by the national budget through MEYS, LRI CZECRIN (LM2023049) and ERASMUS+ (project GREEN-TRIALS, 2025-1-CZ01-KA220-HED-000355652).

Acknowledgements:
On behalf of the consortium of partners in the ERASMUS+ GREEN-TRIALS project: Frances Shiely, University College Cork; Seamus O'Reilly, University College Cork; Sarah Prowse, University College Cork; Vincent Russell, University College Cork; Joana Batuca, NOVA University Lisbon; Zoi Dorothea Pana, University of Nicosia; Martina Esdaile, ECRIN; Amelie Michon, ECRIN; Adriana Papiez, Masaryk University.

Cit. zkr: **Klin Farmakol Farm. 2026;40(2):108-111**
https://**doi**.org/**10.36290/far.2026.021**
Článek přijat redakcí: 30. 3. 2026
Článek přijat k tisku: 1. 6. 2026

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a key target which the sustainability strategies should focus on (1–4).

Recent estimates further illuminate the magnitude of this challenge. If the „mortality cost of carbon" metric shows that 4,434 metric tons of CO_2 lead to one excess death, current healthcare emissions could be associated with approximately 550,000 excess deaths (5). For Europe alone, Chen-Xu et al. estimated that healthcare-related emissions would result in approximately 365,047 DALYs and 25.6 billion euros in healthcare costs, assuming that no significant changes occur and based on current underlying expectations (4). In addition, projections suggest that without immediate and coordinated action at the systemic level, the healthcare sector's carbon footprint could triple by 2050 (6). In light of these trends, transitioning toward and investing in sustainable and climate-resilient healthcare thus seems necessary because such investments would eliminate or at least reduce the expenditures to address the consequences. Steps towards sustainable healthcare are therefore inevitable.

Support in developing sustainable healthcare and "green" trials

One of the strategic frameworks guiding this change is the Net Zero Initiative. Under this commitment, the participants pledged to reduce their emissions by 45% by 2030 and reach net zero by 2050. The concept of net zero denotes a state in which residual anthropogenic emissions should be minimized to levels that can be absorbed by nature. Thereby no added CO_2 will accumulate in the atmosphere and keep global warming to no more than 1.5 °C (corresponds to the pre-industrial level); all in accordance with the Paris Agreement. As of now, 139 out of 199 countries have formally joined the net zero programme (7, 8).

Parallel to the above-mentioned policy commitment, a number of initiatives aimed at accelerating sustainability within healthcare are currently being established. Within the EU, the primary driver supporting environmentally conscious research is Horizon Europe. Horizon Europe programme (2021–2027), encompassing both the preceding and forthcoming programmes, financially supports climate-neutral research and innovation. Specifically, the following three projects are centred on the development of carbon-neutral and sustainable healthcare systems: *Caring Nature*, *KitNewCare*, and *NetZeroAICT* (9, 10).

The *Caring Nature* project focuses on developing ten innovative solutions aiming to reduce non-supply chain greenhouse gas emissions in the healthcare sector, such as optimized heating, ventilation, air-conditioning and electricity systems, expanded telemedicine, and reduced medical waste. Eleven EU countries, but not Czechia, are participating in this project (11). The *KitNewCare* project is focused on more sustainable kidney care (12). *NetZeroAICT* applies artificial intelligence to computed tomography with digital contrast, which enables to limit contrast media administration to patients (13). In addition, Horizon Europe supports five "green pharmaceutical" projects, aimed at developing innovative sustainable pharmaceutical manufacturing processes, with total funds of 35 million euros (9).

Although none of the initiatives or projects directly targets sustainability in clinical research, it can be assumed that changes from sustainable clinical practice will influence research processes, too, given the interdependence between healthcare delivery and clinical research. Advances in one domain can be expected to propagate into the other, facilitating broader transformation toward environmentally responsible healthcare.

Sustainability in clinical trials

Clinical trials represent a complex, resource-intensive component of healthcare and clinical research. Their environmental impact has only recently begun to be systematically examined. Specifically, next year marks 20 years since one of the first analyses of the carbon footprint of clinical trials was published. The *Sustainable Trials Study Group* highlighted early that clinical trials contribute substantially to greenhouse gas emissions and emphasized the need for simpler and more efficient trial designs and processes (14). More recently, according to *Sustainable Healthcare Coalition*, an average clinical trial that is registered on clinicaltrials.gov may generate 27.5 million tons of CO_2 emissions, with an estimated total annual emission from all active trials reaching as much as 100 million tons (15, 16). These findings, though still estimates, underscore the urgency of incorporating sustainability principles into trial methodology.

How to define a "green" clinical trial?

Even though no universally accepted definition of a sustainable or "green" clinical trial exists, it can be basically characterized as a clinical trial that systematically minimizes or at least considers environmental harms in each phase of its design and execution while ensuring participants' safety and scientific data integrity. Given the substantial heterogeneity among clinical trials, there are currently no established emission thresholds set on average appropriate/ideal emissions, or total or percentages of emission reduction. The current efforts thus focus on evaluating various mitigation strategies to determine the most effective interventions yielding the lowest possible carbon footprint while maintaining operational feasibility.

Important steps in development of "green" clinical trial, digitization and decentralization of clinical trials

The prerequisite for effective carbon footprint reduction is, first and foremost, the measurement of emissions. Quantitative data allow researchers to identify preferential and high-impact areas, and to prioritize evidence-based mitigation strategies. Energy consumption in research facilities, travelling and distribution, and inefficiencies in protocol design (that can, for example, increase staffing needs) were expected to be the most significant contributors and should thus play a key role in the strategies of reducing CO_2 emissions. This was confirmed by the *Sustainable Trials Study Group* (14). To support emission estimation, the National Institute for Health and Care Research (NIHR), in cooperation with the *industry Low-Carbon Clinical Trials* (iLCCT) consortium, has developed and published a carbon calculator – available on the website https://clinicaltrialcarbon.org/ (17–19). The calculator provides approximate assessments of the carbon footprint based on the trial design. While the calculator captures carbon output,

it does not encompass broader ecological aspects. Therefore, emissions estimates are likely underrepresented and the total ecological impact will be even higher (17, 20). Further progress can then be made in accordance with the strategies set out in various guidance documents.

In the context of the above-mentioned information, digital and decentralized clinical trial (DCT) models should offer one of the most effective approaches for reducing carbon emissions. Kohl et al. estimate that typical paper-based study can lead to approximately 4,885 kg of CO_2; transitioning to a fully digitized clinical trial can reduce emissions by approximately 90%. Digitization alone (by migrating informed consent forms, forms and questionnaires, case report forms, and essential documents such as master files and site files to electronic platforms) can eliminate the need for vast amounts of paper – up to 164,800 sheets of paper in an average clinical trial (equivalent roughly to a stack of paper higher than 16 metres and 799 kg CO_2) (21). Decentralization facilitates remote data collection by allowing participants to complete some study procedures without travelling to clinical trial sites, with telemedicine consultations replacing in-person visits. This model not only reduces emissions – an estimated 237 kg of CO_2 emissions per an average clinical trial with 9 visits – but also decreases the time and financial burden placed on participants. Remote physiological monitoring (e.g., blood pressure or heart rate) can be performed using digital health technologies and wearables, offering additional benefits such as longitudinal monitoring, monitoring in real-world environments, and immediate transmission to investigators. Biological samples, such as saliva, stool or urine, can be collected via courier services and delivered directly to laboratories, while the sample-collection materials can be sent directly to participants. Clinical research associates can likewise conduct site oversight remotely through virtual meetings. It can save an additional 3,808 kg of CO_2 per average clinical trial with five monitoring visits of each of ten centres by car depending on travelling distance (16, 21, 22). Beyond these approaches, other emerging trends (e.g., integration of artificial intelligence for trial optimization, increased use of real-world data, virtual clinical trials) can be expected to further enhance both the efficiency and environmental performance of clinical trials.

However, DCT models introduce new forms of energy demand – computer and server operation, digital communication, etc. Kohl et al. provided approximate estimates of these alternative sources of emissions: energy needed for filling out questionnaires on computers or smartphones (counted as 1 minute per page), video consultations (approximately 1 hour with each centre), email communication (estimated at 12 per participant), and server operation (assuming 0.04 kW/h) for maintaining the trial platform over a 2-year period. In total, these activities generate an estimated 486 kg of CO_2, which is still substantially less compared to the traditional clinical trial (21). DCTs also support inclusivity, even though disparities in digital literacy, variability in internet access, device validation requirements to bring accurate results, and the need for robust data protection frameworks pose additional challenges (23, 24). Higher initial costs for digital health technologies, alongside other challenges (e.g., resistance from clinical sites, regulatory uncertainties, the need for staff training and infrastructure adaptation) can be another issue. However, ultimately, DCTs have the potential to yield long-term cost savings (16).

An illustration is provided by the PROMOTE study, a DCT conducted during the Covid-19 pandemic among pregnant women. The decentralized design reduced the environmental burden from approximately 123.9 kg of CO2 to 3 kg of CO_2 (a 41-fold reduction). In addition, the decentralized design improved participant recruitment (22).

Regulatory framework, initiatives, and education in the field of "green" clinical trials

Although many countries have committed to achieving net zero by 2050, sustainability considerations for clinical trials are not incorporated in their regulatory frameworks or requirements. Major bodies acknowledge the importance of clinical trial sustainability and have begun to work on guidelines to promote more efficient and lower-carbon trial design (25). However, the absence of binding legal framework means that "greener" trial practices still remain voluntary. Unfortunately, even the ethics committees have not yet received guidelines on how to properly formulate recommendations and assess environmental aspects in clinical trials (25, 26).

Multiple groups and activities are emerging to advance environmental sustainability within clinical research. The *Sustainable Healthcare Coalition* plays a central role in accelerating and amplifying decarbonizing action (27). The strength of their voice in this area is demonstrated by the fact that they were invited to collaborate with the global platform of *Sustainable Markets Initiative* (SMI) (16, 18, 28, 29). Similarly, the *Institute of Cancer Research* (ICR), in collaboration with the NIHR and the UK Clinical Research Collaboration (UKCRC), is actively integrating sustainability principles into healthcare and clinical trial designs (30). SMI and ICR are both part of the *iLCCT consortium* that developed the clinical trials carbon calculator (18, 19). The Medical Research Council and National Institute of Health and Care Research (MRC-NIHR) Trial Methodology Research Partnership has established the *Greener Trials Group* which shares methodologies for reducing emissions, waste, and water use in clinical trials or provides guidance for carbon footprint estimation. Their online resources represent one of the most comprehensive repositories currently available (20, 30, 31). The *Breast International Group* (BIG) is another group active in this field, organizing events to discuss challenges ranging from CO_2 emissions in cancer research to climate-related disruptions of clinical trial operations (32). The Health Research Board of the Trials Methodology Research Network (HRB-TMRN) discussed sustainable clinical trials in their online conference, too (33).

These examples illustrate only a subset of the efforts currently devoted to sustainability in clinical trials. It is encouraging that sustainable clinical research has been gaining increasing recognition. Although many of the above-mentioned groups are primarily based in the UK, they maintain international collaborations and outreach.

Unfortunately, there remains a notable lack of comprehensive, structured training

material on sustainable trial designs. The majority of existing resources have an occasional character and provide useful introductions, but are insufficient given the scale, complexity, and multidisciplinary nature of the challenges of implementing sustainability principles into clinical research (20, 27, 28, 30, 32, 33).

In order to raise awareness of sustainability in clinical trials via education and to address this educational gap, the ERASMUS+ GREEN-TRIALS project had been proposed by the Masaryk University, the University College Cork, the NOVA University Lisbon, the University of Nicosia, and ECRIN and launched as part of the same consortium in November 2025. The GREEN-TRIALS project focuses on integrating sustainability principles into the trial methodology curriculum and creating highly innovative structured learning resources covering the topic from broad perspectives. The GREEN-TRIALS project's primary target population is undergraduate healthcare students, but the curriculum will be adapted for clinical trialists and other professionals more or less directly involved in trial design and oversight. Moreover, the GREEN-TRIALS project places strong emphasis on reach and its own sustainability. The curriculum will be available in English and translated into four other languages. Additionally, each curriculum unit will be accompanied by a teacher's guide. A series of international, free training events will be conducted in 2027 and 2028 to support widespread capacity building.

Conclusion

The findings clearly indicate that both healthcare and clinical research are important contributors to global greenhouse gas emissions, making them priority areas for resource-efficiency and sustainability efforts. Progress in this domain depends on a precise understanding of the emissions associated with specific research processes and on the feasibility of optimizing these processes, too. Although sustainability considerations are only beginning to be systematically integrated into clinical trial methodology, increasing awareness and coordinated stakeholder engagement can significantly accelerate the development of effective solutions. Moreover, sustainable elements in clinical trial design may offer benefits that extend beyond environmental impact reduction – by reducing participant burden, enhancing inclusivity, and improving the feasibility of generating quality data. Integrating sustainability principles into clinical research thus represents an important step toward advancing both scientific rigor and environmental responsibility.

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