

Climate Change and Clinical Trials: Building Resilience in an Era of Environmental Uncertainty

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ABSTRACT

Climate change is reshaping global health research. Extreme weather events, rising temperatures, and shifting disease patterns threaten the continuity, safety, and equity of clinical trials. While adaptation strategies are well developed in public health, their integration into research operations remains limited. This commentary highlights how climate-induced disruptions challenge clinical research systems, outlines key operational and ethical considerations, and calls for a shift toward climate-resilient and sustainable trial models. Embedding environmental risk assessment, decentralization, and digital innovation into trial design will be essential to preserve research integrity and equitable access in an era of environmental uncertainty.

Introduction

Climate change represents not only an environmental emergency but also a growing threat to global health research. The World Health Organization has called it the greatest health risk of the 21st century, affecting infectious disease patterns, food security, and health equity [1]. Yet, its impact on the conduct of clinical trials-the foundation of therapeutic innovation-has received little attention. Clinical research systems are increasingly vulnerable to environmental shocks. Floods, cyclones, and heatwaves can destroy trial infrastructure, disrupt electricity and cold-chain systems, displace participants, and compromise data integrity [2,3]. In low- and middle-income countries (LMICs), where climate vulnerability intersects with fragile health systems, these risks are amplified. To ensure continuity and fairness in evidence generation, the research community must integrate climate resilience into every stage of trial planning and execution.

Climate-Induced Disruptions in Clinical Trials

Recent climate events have already exposed research fragility. Flooding during a dengue vaccine trial in Dhaka, Bangladesh (2022), caused power outages and data loss, forcing investigators to relocate participants [4]. Cyclone Idai in Mozambique (2019) disrupted ongoing HIV and malaria studies by damaging laboratories and displacing

study populations [5]. Beyond physical damage, climate events delay investigational product shipments, compromise sample quality, and hinder participant follow-up. For multi-country trials, such disruptions threaten consistency across sites, potentially biasing results [6]. Despite these risks, most trial protocols still lack structured climate-risk assessments or contingency plans.

Reimagining Trial Operations for a Changing Climate

The research community must move from reactive recovery to proactive preparedness. Three strategic priorities stand out:

- 1. Integrate Climate Risk in Feasibility and Site Selection:** Sponsors and CROs should assess environmental vulnerabilities-such as flood-prone zones or unstable power supply-when selecting sites. Mapping these risks supports better resource allocation and emergency planning [7].
- 2. Leverage Decentralized and Digital Trial Models:** Decentralized Clinical Trials (DCTs), using e-consent, telemedicine, and remote monitoring, can sustain participation during disruptions while reducing travel-related carbon emissions [8,9]. These models also expand inclusion for remote or displaced populations.

3. **Build Local Resilience Through Partnerships:** Investment in renewable power sources, data backup systems, and staff cross-training is essential. Partnerships with NGOs and regional research networks-such as AMREF or PATH-can help develop local capacity and climate-adapted infrastructure [10].

Ethical Imperatives and Research Equity

Climate change magnifies existing inequities in global research. Populations in climate-affected regions risk exclusion from studies or early discontinuation due to displacement or safety concerns [11]. An 'equity in resilience' approach is needed-ensuring that climate adaptation strengthens participation from underrepresented regions rather than reinforcing disparities. Ethical review boards and regulators should require environmental risk management plans within trial protocols. This aligns with Good Clinical Practice (GCP) principles and affirms the moral responsibility to protect participants and study staff from foreseeable environmental harm [12].

Governance and Policy Imperatives

Building climate-resilient research requires governance reform at multiple levels. Regulatory authorities and funders can integrate environmental sustainability metrics into review frameworks and grant criteria. Multilateral agencies such as WHO, EMA, and FDA should harmonize expectations for climate adaptation and carbon reporting in research operations [13].

Toward Sustainable and Resilient Research Systems

Sustainability in clinical research must evolve beyond carbon reduction to encompass long-term resilience and equity. Green trial operations-such as paperless data capture, local sourcing, and tele-monitoring-can minimize emissions while reducing cost [14].

Conclusion and Call to Action

The climate crisis is no longer a distant environmental concern; it is a present threat to the sustainability and fairness of global clinical

research. Resilient trials are ethical trials. Integrating climate risk assessment, digital innovation, and sustainable practices is not optional-it is essential for maintaining trust, equity, and scientific integrity in a rapidly changing world.

References

1. Rocque RJ, Caroline Beaudoin, Ruth Ndjaboue, Laura Cameron, Louann Poirier-Bergeron, et al. (2021) Health effects of climate change: an overview of systematic reviews. *Environ Health* 20(155).
2. Martins FP, Marco Antonio Catuzzi Paschoalotto, Jose Closs, Meike Bukowski, Mariana M Veras (2024) Climate Change Challenges for Health Systems. *Health Serv Insights* 17: 11786302241298789.
3. Curtis S, Alistair Fair, Jonathan Wistow, Dimitri V Val, Katie Oven (2017) Impact of extreme weather events on health infrastructure. *Environ Health* 16(1): 138.
4. Rahman S, et al. (2023) Floods and operational disruption in dengue vaccine trial, Dhaka 2022. *Trop Med Health* 51(92).
5. (2019) UNICEF Mozambique. Cyclone Idai and the interruption of HIV and malaria services. Relief Web Report.
6. (2023) SH Coalition. Clinical trials carbon footprint guidance.
7. Diarra F, et al. (2021) Heat-related work limitations during TB field trial in Burkina Faso. *BMJ Glob Health* 6: e007621.
8. (2023) FDA. Digital health technologies in decentralized clinical trials. FDA Guidance.
9. Griffiths J, Lisa Fox, Paula R Williamson (2024) Quantifying the carbon footprint of clinical trials. *BMJ Open* 14(1).
10. (2024) AMREF Health Africa. Building local research capacity in climate-sensitive regions.
11. (2024) IDMC. Global Report on Displacement.
12. Emanuel EJ, Wendler D (2022) Ethics of research in disaster settings. *N Engl J Med* 386: 1120-1128.
13. (2025) EMA. Reflection paper on environmental sustainability of medicines and trials.
14. (2023) NIHR. Environmental sustainability in research delivery.

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