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# Guidance on Environmental Impact Mitigation in Decentralized Clinical Trials

Decentralized clinical trials (DCTs) have rightly been hailed as a revolutionary approach to conducting clinical research, offering several advantages over traditional models. DCTs are conducted wholly or in part outside of traditional trial sites, with trial-related activities, such as participant visits and monitoring, taking place at alternative locations such as the participants' homes or local healthcare facilities. DCTs have the potential to expand access to more diverse patient populations in addition to making more efficient use of resources. As such DCTs are an increasingly popular choice among sponsors and investigators.

However, there are several ethical and practical questions and considerations that must be addressed when designing and implementing DCTs. One of the most pressing issues is the increased environmental impact of these styles of trials. For example, a company conducting a decentralized clinical trial may need to ship large quantities of printed materials such as informed consent forms, case report forms, and study brochures to each trial participant instead of a central site. An article measuring the impact of clinical trials showed that "28% of the carbon footprint of a clinical trial is from shipping of investigational products and documents" ^1 highlighting the need to reduce transportation and shipping-related emissions in DCTs. As such the increase in **shipping and transportation of investigational products (IPs) to trial participants will likely lead to greatly increase carbon emissions**, compared to traditional clinical trials, particularly when these products are shipped over long distances.

> **"28% of the carbon footprint of a clinical trial is from shipping of investigational products and documents."**

In order to mitigate the increased environmental impact of decentralized clinical trials, **it is important for companies to take steps to reduce their environmental impact in other areas of the study.** A popular and

effective option is by sourcing all printed documents locally. Local production has been found to provides **a potential saving of 67% of carbon emissions and 3,445 km of shipping distances per order**. Furthermore

environmentally sustainable DCTs. The EU has recently taken steps towards reporting on the specific environmental impact of clinical trials with the Pistoia Alliance leading a targeted outlook on DCT's specifically.

**28%**
How much shipping contributes to the overall carbon footprint of a trial.

**67%**
How much carbon emissions could be reduced by using local production.

**3,445km**
How much shipping distances could shrink by from using local production.

KPMG established through accounting for all emissions from cradle to end customer based on a Life Cycle Analysis (LCA) using the EcoInvent database and a physical allocation methodology, that the reductions in CO2 emissions between producing centrally versus locally is 80% on average and up to 90% in specific cases with the production of the documents accounting for only 10-20% of total emissions^(KPMG 2022)

**Local sourcing of printed materials can greatly reduce the cost and carbon footprint associated with global shipping while also providing additional cost savings by reducing the need for shipping related logistics.** This is in comparison to the traditional method of sourcing printed materials from a global supplier and shipping them to each site from one place.

Ultimately regulatory bodies such as the Food and Drug Administration (FDA) need to develop additional guidelines and best practices for conducting

## *In Conclusion*

Decentralized clinical trials offer many benefits to patients and researchers. However, they also have the potential to increase the environmental impact of clinical trials by increased shipping and transportation of materials. **Companies must begin taking steps to reduce their impact in other areas of the study, such as locally sourcing printed materials companies to help mitigate any increased environmental impact of decentralized clinical trials while still realizing the benefits of this innovative approach.**

As clinical trials continue to shift towards this decentralized model, companies must adopt a proven approach to rethink and re-engineer the process. Partnering with a trusted provider, like docs24, to implement a global/local model can provide significant benefits to trial sponsors and healthcare professionals running the trial.

These include:

- Direct cost savings on shipping costs and elimination of shipping related logistics.
- Improved efficiency and productivity for site staff, who can spend less time on document-related administrative tasks and more time focused on the core aspects of the trial.
- Streamlined trial operations and improved efficiencies.
- Reduced carbon footprint and environmental impact, which can improve a company's reputation while mitigating the increased emissions from decentralized trials.

It's essential that all parties involved understand the clinical and regulatory domains to anticipate the specific needs of the DCT process. By providing a central expertise hub that can automate production to pre-vetted vendors local to the country required, **docs24**. can assist in making decentralized clinical trials more efficient, cost-effective, and environmentally sustainable. While sponsors can reap significant benefits and move closer to a healthier planet.

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### *About docs24*

We provide tech-enabled document solutions for CROs, Pharma and medical device companies.

Our solutions streamline the process from creation through to print and delivery.

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### *References*

Sustainable Trials Study Group (2007). Towards sustainable clinical trials. BMJ (Clinical research ed.), 334(7595), 671–673. https://doi.org/10.1136/bmj.39140.623137.BE

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