WHITE PAPER

Driving a Sustainable Future in Clinical Trials through Decentralized Trial Models

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Many biopharmaceutical organizations are committed to reducing their carbon footprints in alignment with the United Nations Paris Agreement. However, achieving these goals without compromising safety, quality, or development timelines is no small act and will require organization-wide focus and innovative solutions implemented toward near- and long-term goals. Modern clinical trials pose a complex and matrixed challenge for our community as we work to lower the greenhouse gas emissions (GHG) of trials. Emissions are additive, and contributions from many different organizations, patients, healthcare professionals, and all others matter. We all must work together toward a common goal.

As we consider a problem as intricate as anthropogenic global climate change and environmental conservation, it is easy to be paralyzed by the complexity of the problem and the need to track every single source of GHG emissions. While everything from disposable gloves to investigational product has a carbon footprint, we must not miss the larger goal among the data points. With so many people involved in clinical research, we all have a meaningful responsibility to identify opportunities for carbon footprint reductions that can be made centrally through innovative strategies but also at the individual level through small actions. To put it in perspective, the average car emits about 4.6 metric tons of carbon dioxide per year.[1] Considering the collective emissions from clinical trials, the impact can be akin to nearly 22 million of cars on the road annually.[2] This number is slightly more than the number of cars in the whole of Australia.[3] Addressing the carbon footprint of clinical trials is a vital piece of our species' global efforts to reduce carbon emissions and flag climate change.

Herein, we offer some strategies for modernizing clinical trials today and ways to reduce the carbon footprint of our clinical trial activities. As an industry, we must collectively commit to an environmental Hippocratic Oath, striving to minimize our impact on the planet as we advance medical research. This is a nuanced problem: we as an industry are generating GHG emissions, landfill waste and polluting water, while developing lifesaving therapies. The modern world is not so black and white.

While we urge drug developers and patients to demand greater transparency and sustainability across the pharmaceutical supply chain, the PPD® clinical research business of Thermo Fisher Scientific is taking a leadership position in conducting more sustainable clinical trials. PPD recently announced a four-pillar sustainability strategy for clinical studies, including developing predictive models and analysis tools, identifying strategies for reducing GHG emissions, and increasing patient and site engagement, as well as awareness across all stakeholders. We recently launched a new environmental awareness campaign, One Patient, One Tree, which works to engage patients, sites, and sponsors by planting a tree for every patient enrolled at a PPD site (Phases I through IV).

Modern Trials and Scope 3 Emissions

Today, many biopharmaceutical companies have established net-zero emissions goals and other specific targets around carbon footprint reduction to align with the United Nations Paris Agreement (COP21) and other country- and region-specific sustainability initiatives and coalitions. For example, Thermo Fisher — and the PPD clinical research business — was among the first companies in our sector to receive Science Based Target initiative (SBTi) validation for near-term and net-zero climate goals to maintain global warming under 1.5oC.

Three distinct pathways have been established by the Greenhouse Gas Protocol, an internationally recognized accounting tool, to define and thus allow us to address sources of emissions.[4] Scope 1 includes GHG emissions directly created by business operations, such as refrigerant use, company vehicles, and on-site heating boilers. Scope 2 comprises emissions generated by electricity consumption related to business operations. Both Scope 1 and 2 emissions are more readily identifiable and are generally addressed more quickly with existing technologies: replacing fossil fuels with renewable energy (e.g., nuclear, hydroelectric, wind, solar), replacing older refrigerants with new materials with low global warming potential, switching company fleets to electric vehicles, and so on. Many pharmaceutical companies have implemented solutions to reduce or control Scope 1 and 2 emissions or are in the process of doing so to align with the Paris Agreement's goal of a 45% reduction by 2030.

However, addressing Scope 3 emissions presents its own set of challenges, as the indirect emissions associated with a company's operations, both upstream and downstream, can be difficult to calculate, and managing them can be intricate and confusing.

For pharmaceutical companies, these emissions stem from equipment, raw materials, and services provided by contract service providers and suppliers. They can even encompass factors as broad as the vehicle a patient uses to drive to the pharmacy for their prescription. On average, Scope 3 emissions account for over 80% of the total carbon footprint for a biopharmaceutical company.5

Because of the magnitude of Scope 3 emissions, we as an industry must modernize clinical trial activity to approximate, tabulate, and report these emissions; as well as to meaningfully reduce them with digital and decentralized trials, remote monitoring, reduced travel to the site, near-patient solutions, or other strategies that meaningfully reduce the key sources of emissions with the added benefit of reducing patient burden.

Regulators, investors, and patients are asking more questions about sustainability efforts, and sponsors are discussing sustainability ideas with their vendors and taking the first steps toward addressing Scope 3 emissions within clinical trials.

Drivers for Change Must Come from the Top and the Bottom

Since clinical development activities are driven by sponsor organizations, they are by necessity the primary engine for improving sustainability performance across the industry. Sponsors have the responsibility to make sustainability a priority and demand and support suppliers, including clinical research organizations (CROs), to take appreciable actions to measure and reduce the carbon footprint while maintaining the highest quality across their operations. Since these are considered Scope 3 emissions for the pharmaceutical companies, they must do their best to understand these sources of emissions. Sponsors need to require vendors to address sustainability issues in any proposals they offer, whether that is a CRO presenting a plan for a decentralized clinical trial (DCT) or an equipment or raw material supplier. CROs can identify ways to make processes more efficient.

Of course, CROs, as well as clinical trial sites, physicians, and patients, can also take more steps individually with respect to improving sustainability. CROs can push their vendors to do more — by asking them to consider how they can reduce their carbon footprint and resource consumption — not through offsets (which are not in line with SBTi's guidance) but through reductions. We like to consider the carbon management hierarchy: avoid, reduce, substitute.

Several crucial groups play roles in driving sustainability improvements, including both the investor community and patients. According to the Global Sustainable Investment Alliance, there is over $35 trillion in sustainable assets across five major financial markets. Investors are putting substantial pressure on the companies they fund to address their environmental footprint. This pressure comes in response to a growing interest from the public in investing in sustainable funds and other opportunities with socially and environmentally responsible companies. At the same time, patients and consumers are becoming increasingly conscious of their choices, favoring businesses that prioritize sustainability. Their collective demand for more sustainable products and practices further propels companies toward adopting sustainable measures.

Ultimately, regardless of its geographic location or its position in the supply chain, every organization faces the same challenges with respect to global climate change, and global solutions will be necessary to address these problems. It will require effort from all of us — including patients, principal investigators, clinical trial sites, vendors of all types, and sponsors — as well as continued transformation in decarbonized electrical grids, improved access to electronic vehicles and public transportation, and other "non-clinical trials" systems on which we are dependent.

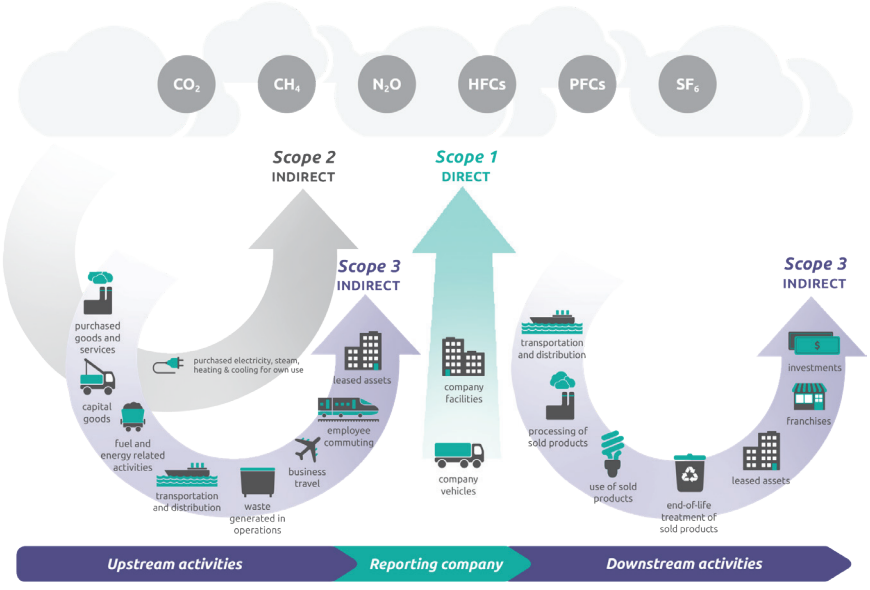

Figure 1: Overview of GHG Protocol scopes and emissions across the value chain[4]

Advancing Environmental Sustainability Through Decentralized Clinical Trials

Decarbonizing clinical trials requires introducing changes within the framework of a strong, robust study design that will provide reliable data upon which safety and efficacy decisions can be made. For example, avoiding protocol creep, utilizing synthetic control arms, reducing patient numbers, and eliminating ancillary assessments that are not necessary to thoroughly evaluate the drug candidate can make huge strides toward reducing the GHG footprint of a study. That said, these changes must be considered thoughtfully to avoid jeopardizing the intent of the trial.

An effective approach involves shifting away from conventional trials held at centralized trial sites, which necessitate patient travel, to decentralized and digitized clinical trials that bring sites and visits closer to the patient's home. If we can move visits closer to the patient, we can benefit both the patient and the planet.

Additional environmental efficiencies that can be realized through modernized clinical trials include decentralized site management organizations with multiple sites. If we can reduce clinical research associate visits for these "chains" of sites, we can substantially reduce carbon emissions by decreasing the number of evaluative visits. This is an approach PPD is taking today. Our internal data shows that an average CRA visit in North America has a carbon footprint of 500 kg of CO2e (or about 23 trees worth of annual carbon sequestration), making every visit meaningful and worthy of thoughtful consideration.

Beyond the DCT framework itself, there are additional opportunities to leverage environmental efficiencies realized in day-to-day living within clinical trials. Some examples are the use of electric cars, renewable power obtained through renewable energy credits, power-purchasing agreements (nuclear, hydroelectric, solar, and wind) specifically established for small businesses, use of public transportation, and increased recycling.

PPD and Thermo Fisher Scientific's Four-Pillar Approach to Sustainability

PPD® is uniquely positioned as a leader in sustainable CRO innovation as part of Thermo Fisher Scientific, which provides products and services to the life sciences sector at large. Together, we have committed to reducing Scope 1 and 2 greenhouse gas emissions by more than 50% by 2030 and to achieving net-zero emissions across the entire enterprise by 2050 (including Scope 1, 2 and 3 emissions). Near- and long-term net-zero targets have all been validated by the SBTi.

At PPD, we focus on four key pillars. The first pillar is the development of models for predicting carbon emissions for clinical studies prior to enrollment. Our models provide insights into the largest carbon emission sources, with the ultimate objective to predict emissions across all sources.

Second, we are working to establish a means for carbon accounting, where the actual and approximate emissions from clinical studies can be calculated and reported to sponsor firms. These results can then be used to enhance the accuracy of the predictive model.

Third, we will use the models and analysis to identify opportunities for reducing emissions and thus establish the ability to better design sustainability into clinical trial protocols from the outset.

Underlying these three areas, our fourth pillar is centered on including stakeholders throughout the industry, ranging from sponsors to patients, with the goal of increasing awareness. It also includes collaborating with vendors and investigator sites to develop innovative solutions for understanding the contributors to clinical study carbon footprints and to minimize them as much as possible.

Collaboration is Key

Collaboration is essential to tackling a planet-wide problem like climate change. We must all consider our footprint and be transparent with all of our partners involved in clinical trials. Small individual changes can, when accumulated, contribute significantly to reducing the carbon footprint of clinical studies. Getting people involved, developing new ideas, and thinking about how we can all help improve sustainability are crucial to achieving measurable improvements as an industry. Everyone must adopt a sustainability-oriented mindset.

In the push toward more sustainable clinical trials, DCT models stand out as a particularly sustainable approach. Through its ecosystem of DCT services, Thermo Fisher's PPD® clinical research business is working to advance sustainability goals, along with a host of other benefits like reduced patient burden, reduced trial failures, cost savings, and more robust and representative data. Optimizing the sustainability of clinical trials requires a comprehensive strategy that predicts and mitigates carbon emissions through patient engagement and digital innovations. This effort echoes broader sustainability commitments, harmonizing with global targets for carbon reduction.

Conclusion

Addressing the environmental impact of clinical trials is a complex but crucial challenge that demands collective action across the biopharmaceutical industry. Embracing decentralized trial models and innovative approaches, such as reducing patient travel and enhancing site management, offers opportunities to lower greenhouse gas emissions without compromising safety or quality. PPD, in partnership with Thermo Fisher Scientific, is at the forefront of sustainability efforts, employing a four-pillar strategy to predict, account for, reduce, and engage stakeholders in emissions reduction. As we strive to balance medical advancements with environmental responsibility, we urge all stakeholders, from patients and investigators to vendors and sponsors, to adopt a sustainability-oriented mindset and work together to measurably reduce the carbon footprint of clinical trials, contributing to broader global sustainability goals.

Learn more about how PPD is creating a healthy planet to support healthy patients.

References

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One Patient, One Tree

We are proud to have recently launched *One Patient, One Tree.* Every time a patient is enrolled at a PPD site (Phases I through IV), we plant a tree with the intention to spark a change in all of us and raise awareness across the clinical trial continuum, as well as spur them to initiate their own projects or change one thing about their daily actions that can have a positive impact.

In partnership with One Tree Planted, we are planting trees in urban areas, like near our Phase I site in Austin, Texas; to help reduce the urban heat-island effect, increase shade, and improve people's lives. We are also helping plant fruit trees in Africa as a means for creating agricultural jobs in economically distraught areas, which helps improve economic outlook and decrease deforestation for charcoal. Mangrove planting in India, Cambodia, and South America, which we also support, helps protect shorelines from damage due to extreme weather events, such as hurricanes.

Tree planting does not just help the environment; it can improve health equity and quality of life and enhance economic opportunities.

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