AI, DATA AND PARTNERSHIPS: THE BUILDING BLOCKS FOR MORE SUSTAINABLE CLINICAL TRIALS

Sas Maheswaran at CluePoints discusses how artificial intelligence, data and strategic partnerships can make clinical trials more sustainable – both financially and environmentally.

"ENVIRONMENTAL IMPACT IS FELT AT ALL STAGES OF PRODUCTION, FROM NATURAL RESOURCE EXTRACTION TO END-OF-LIFE, MEANING THAT THE INDUSTRY IS FACING AN INCREASING ENVIRONMENTAL IMPACT AS THE MARKET CONTINUES TO GROW."

Artificial intelligence (AI) and sustainability are hot topics in the clinical trials industry. More than 80% of current AI users, and 70% of non-users, expect AI to have a significant impact in drug discovery over the next few years.[1] At the same time, there are increasing calls for collective action to reduce the environmental impact of drug delivery devices[2] and late-stage clinical trials.[3]

Increasingly, these important areas are being discussed while AI is being recognised as a pathway towards sustainable and optimised drug development[4] and clinical trial research. This pathway is made up of three interlocking blocks – the AI technology itself, big data and strategic partnerships. All three are vital if the industry is to embrace the opportunities on offer and create a more sustainable future for clinical trials.

WHY DO WE NEED TO MAKE CLINICAL TRIALS MORE SUSTAINABLE?

The global drug delivery devices market was valued at US$42.71 billion (£33.3 billion) in 2023 and is projected to reach $63.38 billion by 2032.[5] Environmental impact is felt at all stages of production, from natural resource extraction to end-of-life, meaning that the industry is facing an increasing environmental impact as the market continues to grow.

The pharmaceutical industry generates approximately 52 megatons of CO_2 annually.[6] Around 70–80% of its carbon footprint is generated by manufacturing processes.[7] However, clinical trials also result in significant emissions, with the largest contributors including site monitoring, drug supply, study team facilities and sample lifecycles.[3]

It is vital to explore ways to make drug development and clinical trials more efficient if the industry is to meet the requirements of the Paris Agreement.

There are also ethical and business imperatives for taking action. Increasing climate change will have a huge impact on population health, driving poorer outcomes and increasing mortality and health inequality.[8] From a business perspective, streamlining processes to reduce environmental impact can also reduce costs.

The importance of sustainability is recognised industry-wide, with pharma companies coming together to highlight areas of environmental, social and corporate governance that need prioritising.[9] Regulators are also increasing pressure on pharmaceutical companies to progress their sustainability goals. For example, in Europe this includes directives on corporate sustainability due diligence[10] and industrial emissions.[11]

COMBINING AI AND DATA TO MAKE CLINICAL TRIALS MORE SUSTAINABLE

By collecting data in a way that enhances recruitment, adherence and data analysis, AI has the potential to accelerate clinical trial cycles[12] and reduce the main drivers of carbon footprint impact.

For example, the impact of a site monitor on the carbon footprint of a trial is dominated by car travel to trial sites.[3] By using AI-powered adaptive site monitoring, sponsors and contract research

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organisations can improve their ability to evaluate the performance of clinical trial sites and adjust site visitation plans more effectively and efficiently.

Increasing the efficiency of clinical trials also has the potential to decrease other areas of impact. For example, by managing trial risks and accelerating resolution with AI-powered risk-based quality management (RBQM) tools, carbon hotspots – such as trial team commutes and energy use in facilities – can be reduced.

USING AI TO ENHANCE DRUG DEVELOPMENT AND REDUCE ENVIRONMENTAL BURDEN

AI algorithms can also enhance drug development because their ability to analyse complex relationships between drug properties, formulation components and physiological factors enables the prediction of drug behaviour at scale. This allows for a more comprehensive understanding of drug delivery mechanisms while aiding the design of efficient delivery systems.[13] Comprehensive AI models can enable the industry to embrace data-driven and personalised medicines, as well as streamline key steps of clinical trial design.[14] Combined, AI and big data can increase speed and efficiency, reducing the environmental burden.[15]

Machine learning (ML) can bring together large volumes of structured and unstructured data to pinpoint relevant information more quickly. This allows study teams to rapidly identify critical-to-success issues and, hopefully, reduce clinical trial failure rate. Given the time and cost it takes to design drug delivery systems, fewer failures would have a dramatic effect on the economy of drug development.

REDUCING TRIAL TIMELINES AND COSTS

The traditional data management model is struggling to cope with rapidly increasing data sources and volumes. Two-thirds of clinical data management personnel experience problems with manual data management processes,[16] which are subject to human error and may not be as effective for spotting critical issues. Source data verification is a drain on time and staff resources, yet it accounts for only 2.4% of critical data queries.[17] Average study close-out cycle time – from last patient last visit to database lock – is more than 36 days.[18]

These shortcomings significantly increase the time and cost required to bring a new product to market. On average, the journey from discovery to market takes 12 years; however, in newer areas of medicine, it can take up to 30 years.[19] New technologies provide opportunities for streamlining the data management model and making development more sustainable.

For example, an unsupervised ML model can offer up to 98% accuracy in query detection. This reduces the amount of "noise" that data managers have to review, allowing them to focus on critical-to-success queries. This, in turn, allows earlier and easier identification of any potential medical or patient safety issues with drug delivery devices.

USING AI TO CONSIDER SUSTAINABILITY

The same attributes that allow ML models to streamline data management also make them the ideal tool to help pharmaceutical companies consider sustainability throughout the drug development process. Identifying, evaluating and optimising each step in the drug discovery process requires evaluation of multiple data points from diverse sources. AI can analyse this disparate data and enable scenario modelling to unlock the potential for more sustainable design. The design principles of cost reduction, therapeutic benefit and ease of use can harmonise with lowered environmental impact.

AI can also be used to identify drugs that may be suitable for repurposing, by identifying a new therapeutic target and predicting a new therapeutic use.[20] Given the high environmental impact of developing from scratch, this, again, has the potential to increase sustainability.

ADDRESSING CONCERNS ABOUT AI EMISSIONS

While AI can be successfully used to increase sustainability in drug development and clinical trials, it is important to recognise the environmental impact of the technology itself. The data centres that house AI infrastructure are often large consumers of water and electricity, leading to increased emissions. They also rely on critical minerals and rare elements that may be mined unsustainably.[21]

The United Nations Environment Programme has made a series of recommendations to help overcome these issues.[22] They include making AI algorithms more efficient to reduce their demand for energy, recycling water and reusing components where feasible, while greening data centres by using renewable energy and offsetting carbon emissions.

WHY DO PARTNERSHIPS MATTER?

Cross-industry collaboration has been identified as a crucial action to secure a more sustainable future for the pharmaceutical industry.[23] AI is a broad discipline with almost unlimited applications. It is therefore vital that pharma companies and sponsors work with specialist partners who can help identify the right types of AI to maximise data use and streamline activities, ultimately reducing the environmental impact of research and development.

"THE DESIGN PRINCIPLES OF COST REDUCTION, THERAPEUTIC BENEFIT AND EASE OF USE CAN HARMONISE WITH DESIGNING FOR ENVIRONMENTAL IMPACT."

Given concerns about the environmental impact of AI itself, it is also vital to work with industry leaders who are developing best-in-class efficient algorithms and who promote renewable practices.

Collaboration is equally crucial when it comes to keeping a focus on sustainability, yet regulations and infrastructure to support sustainable device design, procurement and manufacturing vary globally. The industry needs to build partnerships at scale to reduce costs to individual organisations and enable it to consider the whole lifecycle of devices, as well as embedding more efficient processes throughout clinical trials.

CONCLUSION

Sustainability needs to move from being a topic that individual leaders or departments consider, to an integral part of every stage of drug development and clinical trials. This requires both cross-sector and cross-organisational collaboration.

"WE NEED TO BUILD PARTNERSHIPS AT SCALE TO REDUCE COSTS TO INDIVIDUAL ORGANISATIONS AND ENABLE US TO CONSIDER THE WHOLE LIFECYCLE OF DEVICES, AS WELL AS EMBEDDING MORE EFFICIENT PROCESSES THROUGHOUT CLINICAL TRIALS."

By creating effective strategic partnerships that combine expert knowledge with the latest technology, we can make the most of the opportunities offered by artificial intelligence and big data to secure a more sustainable future for drug discovery and the wider clinical trials industry.

ABOUT THE COMPANY

CluePoints is a risk-based quality management (RBQM) and data quality oversight software provider, harnessing the potential of artificial intelligence by using advanced statistics and machine learning to determine the quality, accuracy and integrity of clinical trial data both during and after study conduct. Aligned with guidance from the US FDA, EMA and ICH E6 (R3), CluePoints supports central and on-site monitoring, medical review and quality risk management to drive a holistic risk-based strategy in all trials. CluePoints combines the expertise of consultants and cutting-edge technology to facilitate pre-study risk assessments, identify risk controls and implement solutions. CluePoints also assists with adherence to global regulatory guidelines using RBQM technology, resulting in positive clinical development outcomes, increased operational efficiency, lower costs and reduced regulatory submission risk.

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