



Branding Science  
Group

# IF **AI** WILL MAKE THE TREATMENT DECISIONS IN THE FUTURE, WHAT DOES THIS MEAN FOR CLINICAL TRIAL DESIGN NOW?

Our healthcare world is full of examples of how AI could be – or is already – improving diagnosis, treatment, follow-up and the overall patient experience.

So, what if AI algorithms were used to make recommendations for treatment decisions, to support doctors in decision-making?

Experts weighed in on this topic at our recent webinar, including Agathe Acchiardo, a leading health trends and futures expert, Eydyth Comenencia Ortiz, a patient experience and insights expert, and Branding Science's Chris Recaldin and Lucy Ireland.

They pondered what would make new medications stand out for AI algorithms, what changes would be needed in real-world and trial data to allow these algorithms to work effectively, and how this would impact evidence generation strategies.



Read our article below for a round-up of the key talking points, or watch the webinar in full, here...

Watch the webinar



## Setting the stage

Nobody can predict the future, but it can be useful to explore possibilities and prepare for a variety of different scenarios. In this webinar, we imagined a potential future where AI algorithms play a significant role in shaping treatment decisions. The use of AI could lead to vast improvements in the quality and efficiency of healthcare services, with significant potential to optimise and personalise patient care.

While there is tremendous promise, ethical concerns also need to be considered.

## Key ethical concerns

Significant ethical considerations need to be made if AI is to make treatment decisions. Key concerns would likely include:



**Accountability** – who is responsible when AI makes a wrong decision?



**Robust regulatory frameworks** would be required to ensure that AI systems are transparent, fair and subject to rigorous testing before being implemented in clinical settings.



**Ongoing monitoring and validation** of AI systems would also be essential in maintaining trust and efficacy.

This begs the question: in a future where AI algorithms make treatment decisions, how would this impact the way we design and conduct clinical trials?





## Outcome measures – the need for alignment

The need for greater alignment between clinical trial outcome measures and what physicians track in practice could be greater than ever with AI involved. Meaningful patient engagement would be key in ensuring that the selected outcomes capture what matters most to patients.

This could involve a shift towards selection of clinical trial outcome measures that generate richer data sets and better reflect the real-world lived experience of patients. Examples may include endpoints measured at greater frequency or via automated quantitative assessments, the use of wearable technology digital endpoints (to generate data in real time) and expanded use of patient-reported outcomes.

Eydyth noting, during the webinar:

**“It’ll be more important than ever for clinical trial sponsors to thoughtfully incorporate the patient perspective as early as possible in clinical development programmes.”**

Incidentally, trials which incorporate patient feedback in the design process perform better in terms of recruitment and retention so will have more robust data for the AI to make treatment recommendations.



## Diversity in clinical trials – a critical success factor

A broader, more representative data set would be required for the AI to know if a treatment is effective for the population, and the importance of diversity in clinical trials is being increasingly emphasised by regulatory bodies like the FDA.

So, how can we improve diversity in clinical trials? Strategies could include:



Selecting geographically diverse sites



Addressing logistical barriers to participation



Developing culturally appropriate outreach and education materials

When it comes to site selection, convenience and accessibility are crucial for participant recruitment, while partnering with patient advocacy groups and providing logistical support, such as transportation and childcare, can enhance trust and participation rates.



## Geographic considerations – capturing the full spectrum

There could also be potential geographic implications if AI algorithms were trained on data from specific countries or a few expert sites. Ensuring data from both urban and rural sites would be essential in capturing a full spectrum of patient experiences and outcomes.

Agathe noted the importance of geographic considerations during the webinar, saying:

**“If the AI is being trained in a different country, will it be trained on data just captured in the specific country where the algorithm is operating?”**

This, coupled with the push-pull dynamics of having a few expert sites compared to a wider range of sites across countries, could have consequences in terms of site diversity.

Incorporating local data from various countries could make the AI's recommendations more accurate and relevant to different populations. This approach helps mitigate biases and ensures that treatment decisions are equitable across a range of patient groups.



## Looking ahead

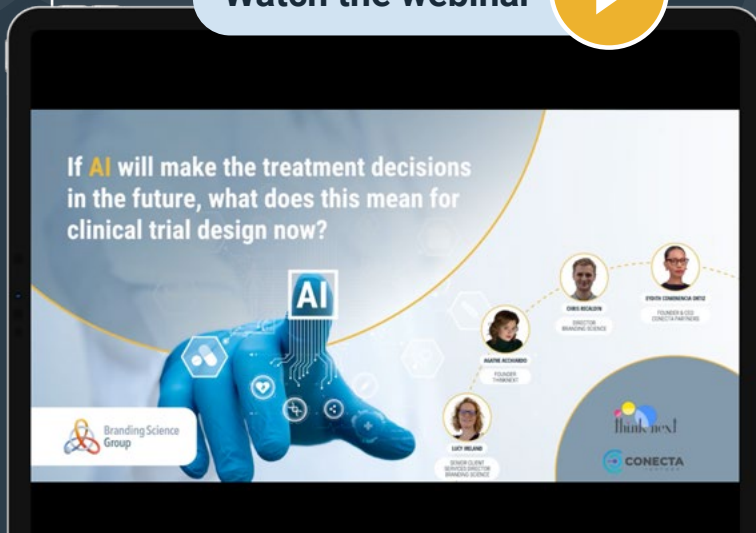
**Exciting possibilities and challenges lie ahead as AI becomes more integrated into healthcare.**

As an industry, it's important to start preparing for a potential future where AI could significantly influence treatment decisions, emphasising the need for diverse and comprehensive data sets in clinical trials.

By embracing these changes and addressing the associated ethical and practical considerations, the industry can move towards a future where clinical trials are more efficient, inclusive and capable of delivering better patient outcomes.

**You can watch our recent webinar on this topic in full, on demand, by clicking below.**

**Watch the webinar**



## Get in touch



**Chris Recaldin**

**Director**

[chris.recaldin@branding-science.com](mailto:chris.recaldin@branding-science.com)



**Lucy Ireland**

**Senior Client Services Director**

[lucy.ireland@branding-science.com](mailto:lucy.ireland@branding-science.com)



**Agathe Acchiardo**

**Foresight Expert, Think Next**

[agathe.acchiardo@thinknext.uk](mailto:agathe.acchiardo@thinknext.uk)

**Visit Think Next website**



**Eydith Comenencia Ortiz**

**Founder & CEO, Conecta Partners**

[eydith@conectapartners.com](mailto:eydith@conectapartners.com)

**Visit CONECTA Partners website**