CT:IQ
Clinical Trials:
Thinking Smarter

Using Artificial Intelligence in clinical trial recruitment

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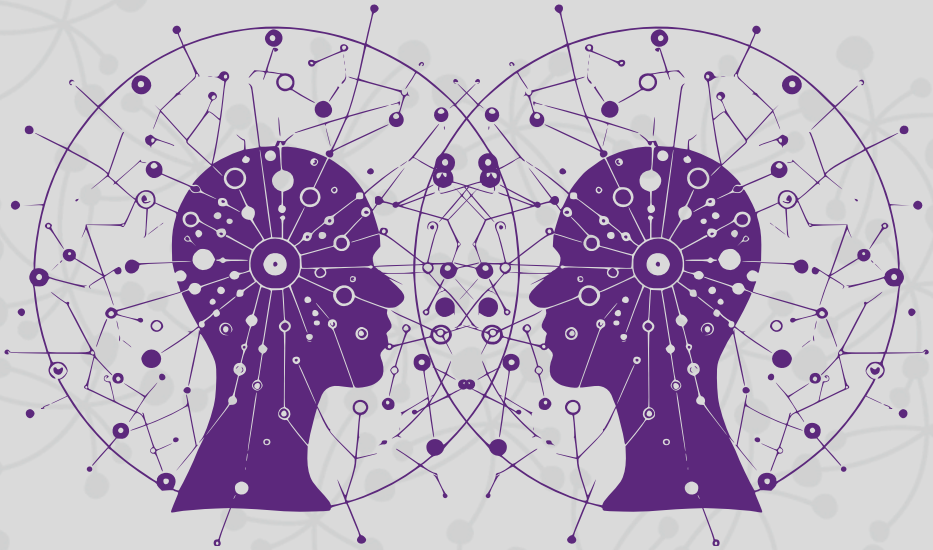

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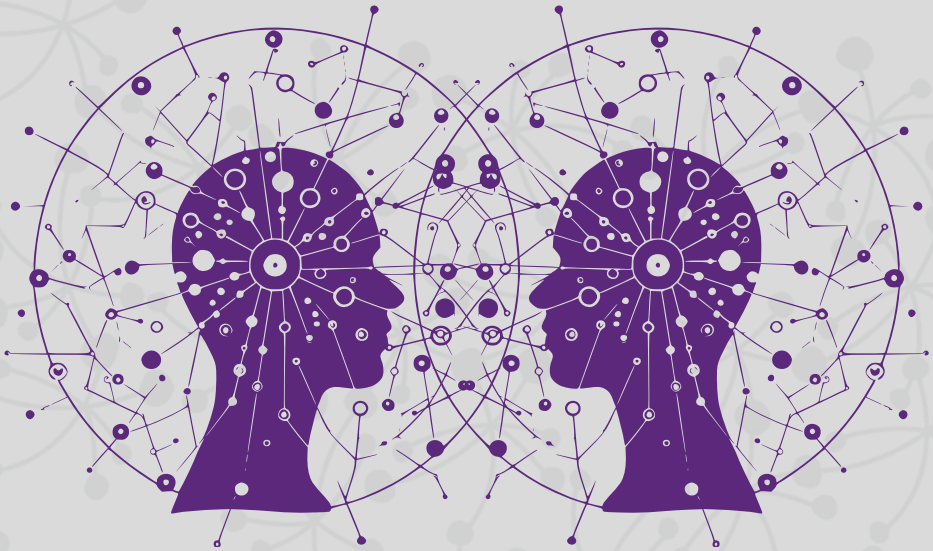

Purpose

This document is an appendix to the CT:IQ Clinical Trial Site Recruitment Guide and looks at how the rapidly changing field of Artificial Intelligence (AI) should be best used when recruiting for clinical trials. The guide provides practical and ethical guidance for site staff and recruiters and will also be of interest to sponsors and investigators looking to use AI as part of their recruitment strategy.

Introduction

Artificial Intelligence (AI) presents opportunities to improve participant recruitment processes. Benefits may include reducing the amount of time recruitment requires at the site level, potentially freeing up investigator and site staff time to have more in-depth interactions with participants; enabling more targeted participant recruitment; increasing the diversity of participants and sites who are approached to take part in a trial; and improving communications with participants and site staff. Some examples of how AI can be used for trial recruitment include:

- Using health records to refine trial protocols by assessing the impact of inclusion/exclusion criteria on recruitment. Criteria that are identified to have a large impact on potential participant numbers can then be reviewed.
- With appropriate legal and ethical authorisations using AI tools to review medical records to identify potential participants. This is likely to be more efficient than relying on site staff to manually screen physical or electronic records. Site staff could then manually screen the AI recommended participants.
- Using AI tools to simplify documents and communication material for site staff and participants, increasing understanding and consistency across sites.
- Developing a chatbot as a triage service for people interested in participating. This could help direct interested people to the right resources, and/or schedule follow-up conversations with site staff.

More examples are discussed in Use cases.

Definitions

AI is broadly defined as the ability of a computer system to perform tasks that would normally require human intelligence. For example, synthesising data from various sources to reach a decision, analysing images, or diagnosing a health condition. Several distinct fields come under this banner:

- **Generative AI (or GenAI)**
  includes Large Language Models (LLM) and Multimodal Foundation Models (MfM). GenAI uses these models to make predictions based on the probabilities seen in its training data. From these predictions, GenAI can create seemingly novel text, images, audio and video.
  - Recruitment examples:
    - Creating simplified communication materials for site staff and participants
    - Development of chatbots as a first line help desk for staff or potentially interested public

- **Machine Learning (ML)**
  allows computers to learn and improve without needing to be explicitly programmed. These algorithms are trained on data to make predictions or decisions. GenAI relies on ML, but not all ML is GenAI.
  - Recruitment examples:
    - Protocol refinement
    - Reviewing healthcare records

- **Natural Language Processing (NLP)**
  algorithms are used to analyse text, comprehend, and converse, allowing them to perform tasks like language translation and question answering. Large Language Models leverage NLP techniques.
  - Recruitment examples:
    - Translation of recruitment materials to different languages
    - Development of help desk resources
    - Analyse unstructured medical data to assess patient eligibility

- ## Computer Vision (CV)

  is used to enable computers to comprehend images and videos like humans, to complete tasks like object detection and face recognition.

  - **Recruitment example:**
    - could be used to verify consent discussions in the future.

Other terms used in this document:

- ## AI Hallucinations

  LLMs may perceive patterns that are non-existent or imperceptible to human observers and may create outputs which are nonsensical or inaccurate. This may be due to overfitting, training data bias or inaccuracy and high model complexity.

- ## Enterprise AI

  is the integration of AI-enabled technologies and techniques within an organisation to enhance business functions. Depending on the settings used, this can greatly increase the security and suitability of the AI tool for an organisation.

- ## Chatbot

  A program designed to simulate human-like conversations and interactions. These use NLPs to understand and respond to inputs (usually texts).

Reference:

- A common understanding: simplified AI definitions from leading standards | Digital NSW, 2025
- Key Terms for AI Governance, IAPP updated July 2025

Overseeing AI

Humans have a key role in establishing appropriate accountability measures to manage risks posed by AI, including by overseeing AI outputs and interactions. This could be through various methods, such as:

- Responsible design. This might include appropriately limiting the use and capability of the AI system to ensure it will only perform approved functions, and enabling human-understandable interfaces.
- “Humans in the loop” where humans are direct participants in all decision making.
- "Humans on the loop” where humans are supervisors and only intervene when necessary.
- "Humans in command" where humans set the overall goals and parameters for the AI system, while it performs the relevant tasks.
- Robust AI governance frameworks.
- AI lifecycle management.
- Regular testing and performance management.
- Embedding systems for anomaly detection.

The most suitable methods of AI oversight will depend on the risks, including to participants. Consider what would happen if participants were incorrectly included or excluded, or if they were given incorrect or misleading information about the trial. These risks must be identified, assessed and guardrails put in place to manage them, before AI systems are deployed for use.

Sponsors and site staff also need to be aware of their level of responsibility for AI outputs. There should be a mechanism for humans to review or override recruitment suggestions if necessary. This includes documenting who is responsible and/or accountable for any issues related to the use of AI in the project. For instance, a list of participants excluded by the AI due to key parameters could be reviewed to check for any unintended exclusions. It is best practice to put in place specific written directions to staff about how AI systems can and cannot be used in their work, including in trial recruitment. This may be through Workplace Directions or AI Use Policies.

References:

- Oversight within the trial team: The Human in the Loop: Why AI Decisions Demand Human Accountability | LinkedIn
- Voluntary principles relevant to the use of AI in general: Australia’s AI Ethics Principles | Australia’s Artificial Intelligence Ethics Principles | Department of Industry Science and Resources

Legal Considerations

As of 2025, Australia does not have AI specific legislation but the use of AI is regulated by several legal frameworks. Work with your institutional IT and legal support services to consider the terms and conditions of third-party AI products and in-house AI systems to ensure they are appropriate. Below are some areas to consider:

- Privacy: Issues arising from collection, use or disclosure of personal information to AI. For example, reviewing or 'mining' patient records will be a secondary use for which an authorisation under Commonwealth and/or State health records law will need to be identified. Seek legal advice and/or review relevant resources, including Office of the Australian Information Commissioner's 'Guidance on Privacy and the Use of Commercially Available AI Products'.
- Intellectual property: Consider whether there is any licence to use any copyright material in the AI.
- Misleading and deceptive conduct: Ensure the AI is being in a used in a way that is accurate and not misleading.
- Current AI best practice: Consider AI Governance best practice, as set out in the Voluntary AI Safety Standard and applicable laws.

Resource:

- The 10 guardrails | Voluntary AI Safety Standard | Department of Industry Science and Resources
- AI Implementation in Hospitals: Legislation, Policy, Guidelines and Principles, and Evidence about Quality and Safety, Australian Commission on Safety and Quality in Health Care 2024

Ethical Considerations

AI is an emerging technology, so the implications of its use in trial recruitment are still becoming apparent. While there is great potential for AI to enhance recruitment processes, researchers and site staff should consider how they will identify and manage risks, including ethical considerations. The National Statement (NS, 2025) does not yet explicitly address the use of AI in recruitment, but of particular relevance are sections on transparency in recruitment strategies and equitable recruitment of participants.

Transparency and privacy in recruitment

The NS, 2025 includes the following requirements that relate to transparency and privacy when using AI systems in recruitment:

- NS 3.1.16: The recruitment strategy must be respectful of potential participants and their culture, traditions and beliefs, and facilitate their voluntary participation.
- NS 3.1.17c: In developing and implementing their recruitment strategy, researchers should consider... any privacy matters relating to the recruitment of participants.
- NS 3.1.18: Researchers should describe and justify their approach to potential participants (i.e. how do they find out about the possibility of participating, or not, in the research). The level of detail that is required by reviewers should be proportional to the foreseeable risks and appropriate to the methodology selected.

AI considerations:

- Perform a Privacy Impact Assessment before inputting information into AI systems.
- Sites and trial recruiters should revise their site Privacy Policy and Collection Notice to ensure they address proposed AI system use and satisfy legal obligations
- Trial recruiters should consider whether it is appropriate to obtain consent for use of personal information by AI systems for trial recruitment. If this is not possible or practicable, they must apply for HREC approval to waive the requirement for consent.
- Understand the limits of data interoperability between medical records from different health services or using different input methods.

- Communicate clearly with participants about how any data generated in the study may be shared with third parties and offer them a choice at the time of collection, where possible, in whether their data might be used to train future AI systems. This includes medical history data that may be assessed in participant selection, and/or data generated during the trial.
- Ensure transparency in the data that has been used to train the AI system. This is important for understanding AI outputs and interpreting the results of those outputs.
- Consider where data is stored by the AI system and retention periods, including that personal information is not stored for longer than necessary.

References:

- MRCT and WCG Framework for Review of Clinical Research involving Artificial intelligence (2025)
- There is also guidance for organisations operating in different jurisdictions, see for example EU guidance:
  - guiding-principles-use-large-language-models-regulatory-science-medicines-regulatory-activities_en.pdf
  - factsheet-four-principles-safe-responsible-use-large-language-models_en.pdf

Equitable recruitment

The NS, 2025 includes the following requirements that relate to ensuring that recruitment is equitable when using AI:

- NS 3.1.13: The criteria for the selection of potential participants for a project and the cohort that is recruited should align with both the objectives and theoretical basis of the research.
- NS 3.1.14: The inclusion/exclusion criteria for the potential participants in a project must be justifiable and should be fair. The exclusion of some groups may amount to unfair discrimination, and/or exclude individuals and groups from the potential benefits of research. Researchers should consider the degree to which including/excluding groups may limit (or compromise) the value of the results of a project, with consequent impact on the merit of the project.

This means that before relying on AI system recommendations for participant recruitment, the investigator and site staff must satisfy themselves that:

- the criteria for the selection of the potential participant pool used by the AI system aligns with the objectives and theoretical basis of the research; and
- the criteria for the potential participants in a project is justifiable and fair.

Use of an AI system in recruitment does not in any way remove or reduce these obligations. It also means that trial recruiters will require a high degree of transparency from the AI systems they use so they can properly assess the criteria applied by the AI system. It is best practice to review recommended participants before proceeding.

AI considerations:

- Ensure that the data used to train the AI is accurate and representative of the people who will take part in the research. For commercially developed AI systems, the training data is likely to have been developed using massive data sets that cannot be reviewed directly. In this case, it is especially important to ensure there are systems for reviewing both the scope of who was included and excluded for any concerning trends.

- Be aware of existing biases in healthcare data (e.g. abelism, sexism, and racism) and understand how AI systems that use this data can reflect and perpetuate these biases. For instance, there are historical biases in how health data has been collected for groups such as Aboriginal and Torres Strait Islander people and people from diverse cultural and ethnic backgrounds. AI systems that use this historic data may inadvertently lead to discriminatory outcomes if their outputs aren't critically reviewed with this in mind.

References:

- Building A Disability-Inclusive AI Ecosystem: A Cross-Disability, Cross-Systems Analysis Of Best Practices - Center for Democracy and Technology
- Australian Health Practitioner Regulation Agency - Meeting your professional obligations when using Artificial Intelligence in healthcare
- Are there systematic barriers to participation in cancer treatment trials by Aboriginal and Torres Strait Islander cancer patients in Australia? - ScienceDirect

Reviewing AI in recruitment

Best Practice Guidance

Site staff and recruiters running trials in Australia should review the AI Voluntary Safety Standard, which outlines best practice approaches to AI governance in Australia at present. Trials may wish to seek legal advice prior to procuring and/or implementing an AI solution in their recruitment process.
Trials to be run in NSW are also encouraged to review any use of AI using the NSW Artificial Intelligence Assessment Framework | Digital NSW. While this framework is not specific to research, it provides a useful guide to assessing the appropriateness of using AI systems.

- Key considerations | Digital NSW
- Artificial Intelligence Ethics Policy | Digital NSW

Researchers and reviewers are also encouraged to review the MRCT and WCG Framework for Review of Clinical Research involving Artificial intelligence (2025). Part D has a checklist on the use of AI for the administration of research, which includes recruitment.

The draft FDA Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products (2025) also provides guidance on what US regulators want to see, including:

- A risk-based approach to validating (and documenting validation of) AI models used. This includes putting in place more stringent guardrails to manage risk in high-risk use cases.
- Ensuring visibility of how AI models operate, including being able to demonstrate the reliability of the models used.

Use cases

Use case	Benefit	Risk
Design optimisation: Test impact of revising inclusion/exclusion criteria on the participant pool	• Initial criteria may be too restrictive or misaligned with real world population. AI can provide a way to pre-test how criteria/protocol can be optimised	• May introduce safety concerns if not sufficient human oversight • May optimise recruitment at the cost of research objectives • Suggested criteria may have unintended discriminatory outcomes
Site selection: algorithms to scan records (social media, EHR, genetic etc) for location of potential participants to inform site selection	• Help determine where sites best placed and likelihood of recruiting sufficient sample size • Replaces time consuming manual searching	• Based on historic data so may introduce inaccuracies (but same true of any other assessment) • Secondary use of data considerations, including inconsistencies between data collection at different sites • Privacy risks of collecting and using personal information

Participant ID: Algorithms to identify and approach potential participants or their clinicians	• Speed of recruitment • Replaces time consuming manual searching • Can look in new places (e.g. social media) potentially increasing diversity • Where applicable, can review eHealth records for likely eligibility • Can increase likelihood that people approached to participate are eligible for the trial	• Risk of distress for participants if approach not carefully considered. • Possible significant privacy risks. Must ensure appropriate authorisations to collect and use data, including secondary use ofdata. • False positives/negatives leading to missed opportunities or inappropriate approach
Staff Engagement and Education: digest complicated protocols into simplified materials for staff (e.g. schedule of activities)	• Easier to understand In/Excl criteria and scheduling etc • Increased consistency across sites • Potential for personalised training based on role in the study • Training in multiple languages to support global trials	• Potential inaccuracies compared to original materials
Participant Engagement and Education: Translation of participant facing materials	• Enable participants from more languages • Cheaper than engaging paid translators.	• Potential inaccuracies • Insufficient or faulty interpretation of local context.

Participant screening: Chatbot for initial screening of participants against key criteria	• Aways available for initial contact by interested parties • Could schedule times for subsequent conversations with site staff	• Potential for initial contacts to be missed or not responded to by site staff • Data privacy concerns (such as name, phone number and health conditions) • Some people not comfortable with chatbot and would want a human alternative • Lacks emotional sensitivity
Participant Engagement and Education: Chatbot for help desk or other personalised participant education	• Available whenever needed by participants • Some participants may be more willing to ask questions of chatbot	• Risk of false information being provided, in breach of laws and ethical duties • Not acceptable to all participants and will need a human backup • Privacy considerations, including in relation to a lack of authorisation to use data harvested for future training (this risk can be removed if the bot is not trained on inputted personal information) • Patients might rely too much on the chatbot and delay reaching out to clinical staff for serious concerns • Lacks emotional sensitivity