

Withdrawal, suspension or termination reasons for AI-assisted clinical trials

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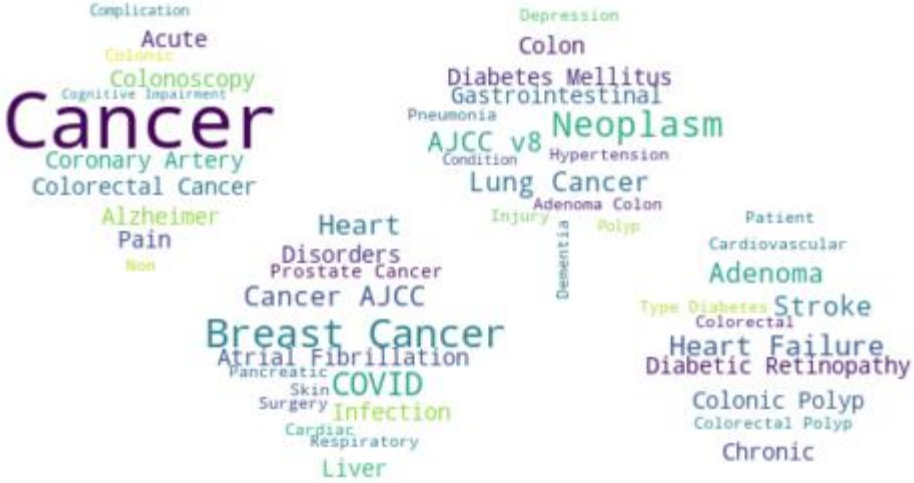
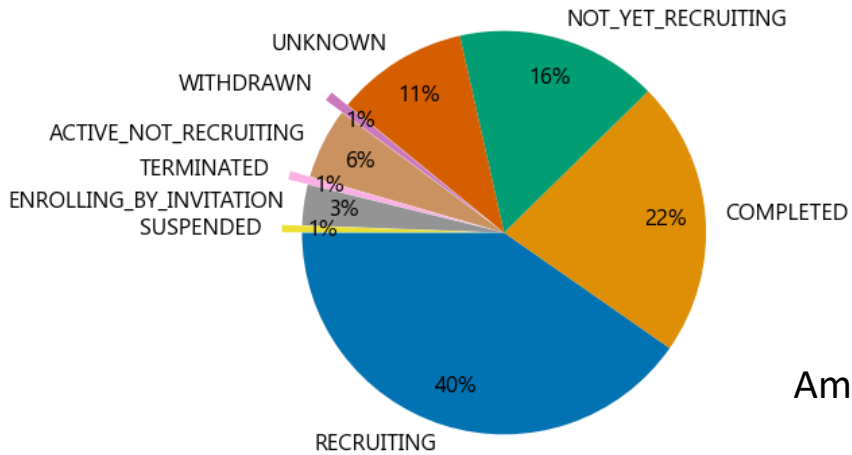
What?

Artificial intelligence (AI) can be described as a computer system performing tasks typically requiring human intelligence. It is a rapidly expanding field, that has already had a significant impact on many areas, including healthcare [1]. However, there are AI-specific challenges to its safe and effective implementation in clinical practice, including data privacy, issues with results generalisation, or technological challenges [2].

Why?

This small study [3] aimed to identify the most common reasons for discontinuation among AI-assisted trials registered in the clinicaltrials.gov database, utilizing a Python-based data processing workflow. A thematic analysis of discontinuation reasons in AI-assisted trials was conducted.

In total, 1,201 (0.2% of all trials) unique AI-assisted trials were found in the clinicaltrials.gov database.



Among all identified trials, the most often assessed conditions included various cancers, heart disease and diabetes.

Out of 1,201 trials, 24 (2%) were suspended, terminated or withdrawn.

- The most common reasons for trial discontinuation included:
- Research barriers (lack of funds, not enough participants): 10
 - Interim results analysis: 4
 - COVID-19: 4

Only two trials were discontinued due to issues related to the implementation of the AI.

Who?

The discontinuation reasons in AI-assisted trials are like those in general trials, but there are trials that were discontinued specifically due to AI-related challenges, including organizational and technological issues.

Author Comments

As the use of AI in clinical trials continues to increase, it will be important to monitor if AI-related issues become a more prominent reason for discontinuation in the future. It will require a multi-disciplinary approach that involves technical experts, ethicists, regulators, and trial sponsors. This collaboration will be crucial in ensuring that AI is used in a safe and effective manner and that the results of the trials are reliable and accurate.

References

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