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WHITEPAPER

Transforming Oncology Clinical Trials

How AI combined with a nationwide clinical data network identifies appropriate trial candidates in minutes.

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Executive Summary

Anyone planning a clinical trial is aware of the increasing time and effort it takes to find and recruit patients that meet the criteria. Prescreening has become a significant source of cost and delay, particularly for oncology trials.

Healthcare professionals lack the time and resources to find and recruit patients who meet trial criteria. Many potentially eligible patients are not identified, let alone informed of their eligibility to participate in a clinical trial.

As a result, principal investigators miss out on the opportunity to gain experience and recognition by running a clinical trial, clinical sites lose the revenue they could have received from the sponsor, and cancer patients fail to gain access to potentially life-saving treatments.

Electronic medical records (EMRs) might seem like a good source to obtain patient screening data from, but EMRs were never intended for such use. Over 80 percent of the data in EMRs is unstructured, in the form of scanned notes, images, and other records. This unstructured data can only be read and understood by medically-trained professionals— no automated system currently available can process and use that data. Thus, many hours of staff time must go into any clinical trial screening effort.

These problems can be solved through the use of an AI-powered pre-screening tool. To be useful, this tool must:

- Extract information from unstructured clinical data
- Automatically de-identify patient records
- Use an oncology-specific natural language processing (NLP) engine to correctly identify clinical information, even when it is not explicit
- Be guided by clinical staff who understand both the use of the tool and oncology clinical practice
- Have access to large, heterogeneous clinical data sets
- Be easily integrated into hospital contracts, operations, and IT functions

Each of these requirements is rare and difficult to meet, yet all of them are necessary for such a tool to be useful for oncology clinical trial prescreening.

The result of an AI-powered pre-screening tool is a faster oncology trial pre-screening process that can vastly increase the pool of clinical trial prospects, keep clinical trials ahead of schedule, increase site revenues, provide more principal investigators with the opportunity to run clinical trials, and give more eligible patients access to new and innovative treatments.

The Overall Problem

With the increasing complexity and specificity of clinical trial eligibility criteria, it has become more difficult and time-consuming to identify recruit the right patients. Many sites fail to find even a single suitable subject for any given trial, and many trials undergo major delays and cost overruns as a result. This causes significant problems for everyone involved in clinical trials, especially the research sites that carry them out.

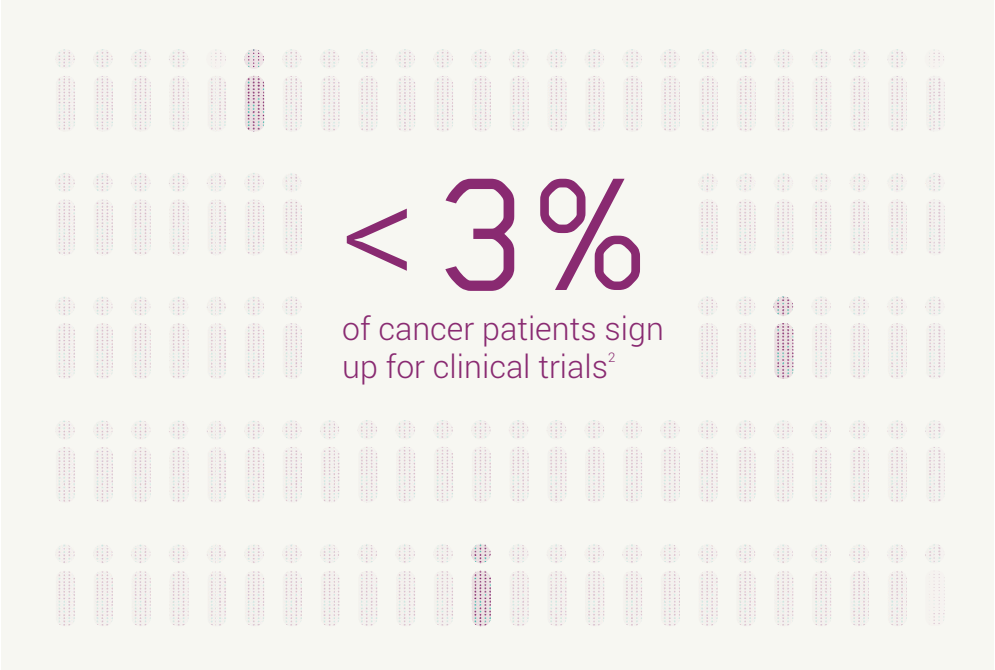
A key source of clinical trial cost and delay is the prescreening process, which involves answering feasibility questionnaires, estimating cohorts, and matching patients to protocols. The difficulties of prescreening can be addressed with AI augmentation.

The Impact

Site staff typically lack the time and the infrastructure to find patients who match protocols.

Eighty percent of clinical trials fail to finish on schedule, and over two-thirds of all trials fail to meet their original patient enrollment targets.[1]

Despite the urgency of many of their conditions, fewer than three percent of cancer patients sign up for clinical trials[2]—and the percentage is even lower for racial and ethnic minorities, patients over 65, and those who live in rural areas.[3]



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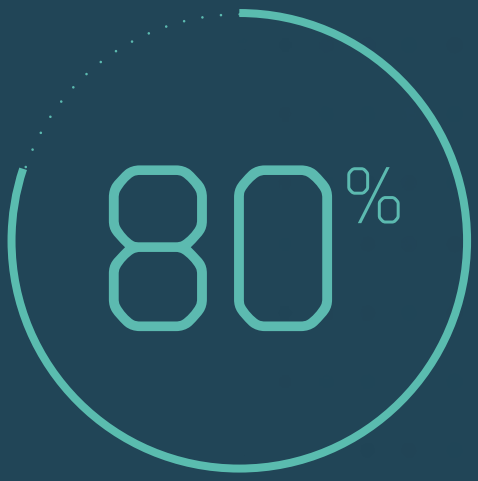

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Over the past five to ten years, cancer treatment has changed significantly, and clinical trials are increasingly recommended as first-line oncology treatments, so this low recruitment rate has negative effects on both current treatment and the development of future treatments. Less than a fifth of cancer patients are ever even informed[4] that there is the option of participating in an oncology trial.

The problems of prescreening are particularly acute outside of academic medical centers (AMC). While AMCs tend to have a larger staff dedicated to clinical trials, community hospitals may have only a single clinical trial coordinator or in some instances, none at all. So, the largest number of potential trial participants is among these facilities. For life sciences companies having trouble getting attention from larger hospitals for trials, community hospitals are a tremendous opportunity for finding suitable patients.

The need for improvement in prescreening for trials is well known, but progress has been limited by difficulties in automating any part of the process, the result of the myriad and varied unstructured clinical data that need to be processed.

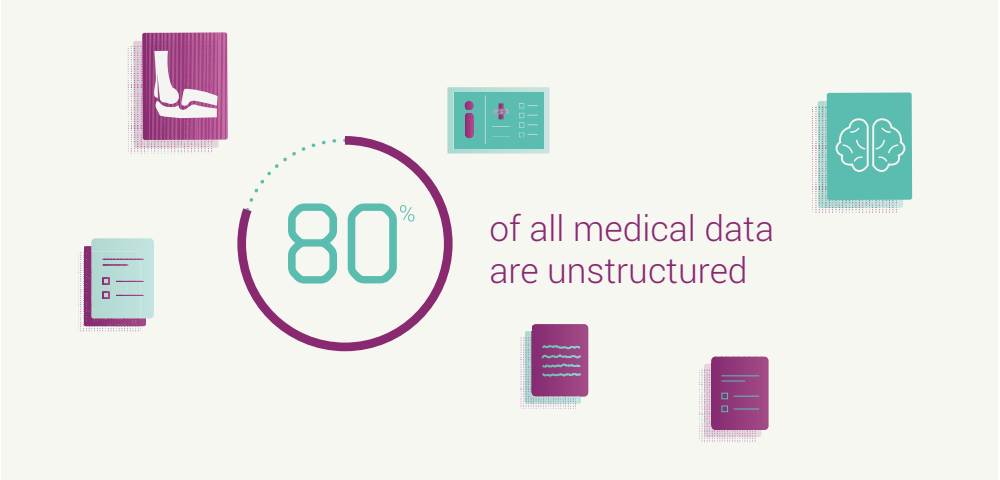
The Shortcomings of Current Solutions

As cancer trials have become more specific in their targets, the criteria have expanded dramatically, which makes it much more difficult to find patients who match all the criteria of a given protocol.[5] In addition, there are significant process challenges with access, normalization, data linking, curation, and governance of data that are required to identify patients.

EMRs were designed to facilitate billing and document provider assessments, activities, and treatment plans. Making diagnostic data widely available for analysis was not their primary purpose. Much of the information in medical records is meant to be read by human beings, not machines.

Over 80 percent of all medical data are unstructured, that is, not meant to be machine readable: free-text notes, scanned documents, and other formats require specialized machine vision and natural language processing (NLP) engines. Yet, these unstructured files hold information essential for effectively identifying patients eligible for clinical trials, especially scanned documents, the most difficult type of document for AI to process.

Due to large amounts of unstructured data, patient prescreening remains a highly manual process. Site staff are left to sift through the documents themselves, a tedious and time-consuming process.

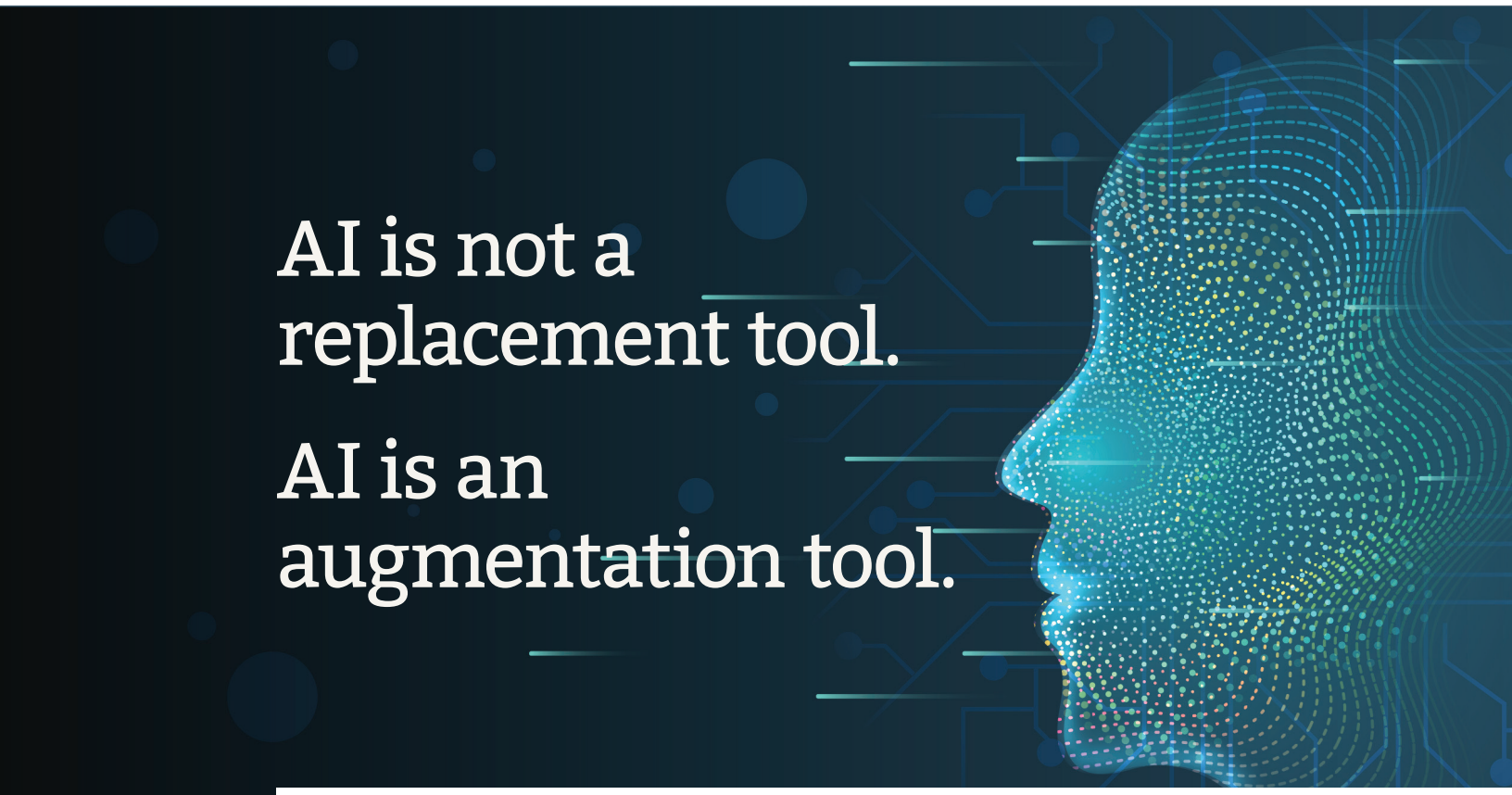


Traditional chart review takes up the bulk of prescreening time, as nurses must scrutinize each patient's chart to determine potential matches, often relying heavily on physicians noting possible patient eligibility during the course of regular treatment, or remembering suitable patients when asked. This can result in many potential matches being missed.

And finally, to ensure a match with study requirements, nurses must go through each prospective patient's medical record, extract the relevant matching attributes, and then combine them with those from all other patients in spreadsheets and databases. This process can take as long as two hours per patient record reviewed.

In summary, the process for prescreening and recruiting appropriate patients for oncology clinical trials is slow, expensive, misses many eligible patients, and imposes significant loads on the resources of already burdened clinics and hospitals. As a result, sites fail to host clinical trials that they would otherwise have the patients and capacity for, or they choose a clinical trial for which they are then unable to provide patients.

The Impact: Principal investigators miss out on the opportunity to gain experience and recognition by running a clinical trial, clinical sites lose the revenue they could have received from the sponsor, and cancer patients fail to gain access to potentially life-saving treatments.



The Necessary Elements of a Solution

How should an AI-based prescreening tool work, and what should it include?

First, the AI must be able to extract information from unstructured clinical data so that it can be effectively queried. Clinical material data such as treatment pathways, disease progression, treatment responsiveness, intent to treatment, intervention types must be extracted at scale from millions of records.

However, information extraction isn't enough. All documents must be redacted for protected health information (PHI). Sites generally do not share open-ended patient information unless it meets HIPAA regulations and any further requirements, at scale. De-identification is a complex and time-consuming task, especially across facilities, vendors, and data sets. Yet, it is a prerequisite for an automated prescreening solution.

Once the patient information has been extracted and de-identified, the AI needs an oncology-specific NLP engine in order to understand which information from a

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patient's records is pertinent for trial matching. Unfortunately, clinical language is often just as unclear, ambiguous, and implicit as ordinary language. This means the AI must be able to disambiguate sentences and infer implied meanings. For example, the AI should be able to tell whether the word 'lung' refers to an organ or operation (it depends on the context) and understand that 'neoplasm in the islets of Langerhans' means the patient has pancreatic cancer.

The more general the AI, the poorer its performance will be when faced with specific tasks of even moderate complexity. As such, off-the-shelf AI engines are likely inadequate to address a highly specialized, complex need.

To function optimally, the AI needs access to two important things: large data sets and distribution channels within the site or medical center. And these forms of access must function smoothly within the existing systems used by principal investigators, research coordinators, and other research staff.

To continually improve, the AI needs large amounts of patient data, from as many sources as possible. As anyone who works in healthcare data knows, this can be a significant obstacle. Much healthcare data is siloed, with separate formats and varying access rules. Establishing contracts with hospitals across the country and getting access to their data would take years and require a significant investment.

In order to bring time, cost, and quality efficiencies to trial recruitment, a network approach to identifying patients is necessary, particularly a network that operates on a nationwide scale and remains vendor and solution agnostic.

Aside from the acquisition of data, integrating AI in clinical settings is a significant challenge. Any new technology relationship will require security reviews, an IP assessment, negotiations around resource allocations, a spot in the budget cycle, and buy-in from everyone, from IT to clinical.

Just as with data distribution, it helps to find a vendor with existing contractual relationships with the facility of interest, since contracting has already been done, trust has been established, and processes have been made operational, which is especially important for the often-overburdened IT department.

IT faces the effort of confirming interoperability, establishing training, and monitoring security, a process that also takes months. If IT is familiar with the data distribution vendor, it is relatively simple to integrate the AI with the existing backbone. No health system wants to use expensive IT resources if they have an existing platform to work with.

The combination of a new model of AI directed at oncology clinical trials and a broad network of facilities and data sources will be transformational. Scalability makes the difference between a small-scale adoption aimed at a few larger facilities and a large-scale adoption over a wide range of hospitals, which would improve results for all.

What to Look for in a Solution

Any potential clinical trial site, principal investigator, or academic medical center needs to consider several factors before adopting a solution to the problems they face with clinical trial recruitment for oncology.

- Find an AI platform that can extract information from unstructured EMR data, de-identify the data with greater-than-human accuracy, organize the data, and make it easily searchable, so that users have access in real time
- Look for an AI solution focused on one therapeutic area
- Make sure the solution has the support of a specially trained clinical team
- Make sure that the solution gives you access to a comprehensive, private clinical trial database
- Take into account administrative, security, and technical delays. Contracting with a company that has an existing network of sites with position inside their firewalls can save months, and even years, of effort

Conclusion

The partnership of Life Image and Mendel.ai provides a clinical trial recruitment solution that meets all of these requirements.

Mendel brings the ability to read and organize unstructured EMR data, anonymize these data, support a site with a team of specially-trained, on-call clinical experts, and a direct (in-software) connection to a comprehensive, private clinical trial database.

Life Image, in partnership with Mendel and a hospital site, provides its standards-based network of clinical data, as well as its relationships and existing integrations within the firewalls of key providers.

Together, they can ensure the speed and accuracy of any oncology clinical trial recruitment effort.

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About Life Image

Life Image is the world's first truly interoperable clinical information exchange network. Our platform ecosystem that benefits every player, including patients, across the healthcare ecosystem, enabling shareability and timely access to patient information at the point of care.

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About Mendel.ai

Mendel.ai is the breakthrough artificial intelligence engine and technology powering Mendel Health. Mendel Health uses deep learning technology to sift through unstructured data in medical literature as well as patient health records, in order to suggest evidence-based treatment options and to continuously update the results whenever a new matching trial or treatment emerges.

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