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Modernizing Key Clinical Trial Processes with Artificial Intelligence

Clinical trials are highly complex, consisting of multiple phases, various stakeholders, loads of documentation, and highly diverse results or endpoints that require deep clinical expertise to evaluate. But they are complex for a reason. These studies are an essential part of the drug and diagnostics discovery and development process, ensuring there is sufficient evidence of safety and effectiveness of a drug or medical device before it's available to the public. It's critical that clinical trials be well-designed, well-controlled, and carefully monitored.

While many aspects of the clinical trial process are understandably arduous, time-consuming and, in some cases, error-prone, there are elements that can be dramatically improved with technology. Artificial intelligence (AI) is one tool coming to the fore with significant potential and many applications in life sciences. In fact, according to a 2021 report from Research and Markets, the global AI-based clinical trials provider market size is expected to reach $5.2 billion by 2028 driven by increasing adoption of technologically advanced solutions for drug development. AI, when incorporated thoughtfully and checked for quality, can help reduce human error and increase efficiencies, ultimately enabling trial sponsors to focus on what matters most — outcomes for patients.

As with any technology employed to support a clinical process, human quality control is essential. This is especially true in clinical trials which require medical expertise and large amounts of data processing, often in the form of PDFs or medical images.

> The stakes are too high for patients to leave decision-making to machines, but AI can lend administrative support that empowers staff and medical experts alike to carry out their jobs more effectively.

Where AI Can Make the Biggest Impact

An important but laborious administrative process in clinical trials that benefits greatly from technology-driven support is the redaction of a participant's personally identifiable information (PII).

PII includes personal health information such as diagnoses, treatment information, and medical test results. It also encompasses demographic information like birth dates, gender and ethnicity which may be obtained, created, used, and/or disclosed during the research process and is protected by law.

As clinical trials often involve thousands of patients across multiple geographies, there is a deluge of PII-rich documentation involved, making redaction a massive undertaking for site personnel. By equipping them with an AI-enabled solution that can automatically detect and redact sensitive patient identifiers, trial sponsors can significantly reduce staff workloads and simultaneously assure that their operations are compliant with strict 21 CFR Part 11 and EU GDPR regulations. AI can also be applied to verify the deidentified source material is associated with the correct patient when researchers upload it for review, minimizing the risk of mistakes that can lead to significant downstream issues.

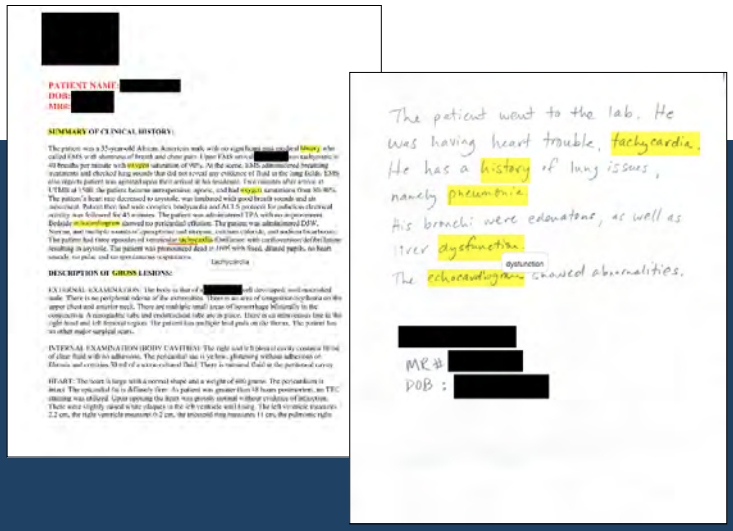
In addition to redacting PII and reducing errors, AI can be employed further along the trial journey for clinical keyword searches to support medical experts adjudicating clinical endpoints or events. Using AI-powered optical character recognition tools, pre-determined keywords pertinent to the trial are automatically highlighted for more efficient review cycles that help adjudicators come to their conclusions more quickly.

Following is a closer look at these aspects of the clinical trial process and how AI technology can deliver value.

Faster, More Precise PII Redaction

AI tools that can reliably identify and redact PII found in a broad range of source materials, including photos, PDFs, and videos, can help propel clinical trials for years to come. This technology can virtually eliminate the longstanding, rampant challenges site-level personnel face when tackling the process manually and free them up to focus on other areas of the trial.

Many site coordinators still handle redaction manually. They use markers to black out sensitive information one page at a time and must often evaluate very small images. This is a time-consuming process, and oversights are inevitable. While software has emerged to improve the process and account for digital source materials, the marker is essentially replaced by a computer mouse, so advances aren't especially noteworthy. With AI-enabled technology, however, this process can be completed in mere minutes with a high level of precision. AI can also be applied to conduct thorough prescreens of source material to verify all PII has been removed before it's uploaded for researchers to review. If AI detects issues, it can automatically alert the site coordinator in real time for a timely resolution.



AI now offers the ability to automatically compare images collected at two timepoints, rather than compare patient names or ID numbers, to verify whether images depict the same individual.

AI offers the benefits of continuously learning and getting "smarter" over time as well. This is appealing to sponsors who know that human site coordinators have varying levels of training and experience as well as high rates of turnover. While a level of human involvement will always be required, particularly in redacting PII from unstructured source material that AI may not be able to recognize, the gains in overall efficiency are undisputable.

From a sponsor perspective, the peace of mind AI-powered redaction offers is invaluable. Documents or images found to contain PII can result in costly and time-consuming queries that delay a trial and leave sponsors liable for noncompliance with privacy regulations. Generally, penalties are based on the extent of negligence and range between $100 and $50,000 per violation, though penalties can reach up to $1.5 million per year in the U.S. and up to €20 million in Europe.

Beyond monetary penalties, the damage that poor protection of patient information can cause to an organization's reputation may be difficult to recover from in the eyes of the market. Trial sponsors understand these risks all too well and are increasingly adopting AI technology not only to safeguard sensitive data, but also to protect themselves and the clinical trial.

Accurate Patient Verification

Once patients' medical images and other source materials are captured and scrubbed of PII, sites must upload them to a central repository for review. Many different site personnel carry out this process over the course of a clinical trial. As each file is uploaded, the patient's name is replaced with a patient ID number, allowing their health to be tracked over time while protecting their privacy.

Historically, if a given image was assigned an incorrect ID number, the error was difficult to detect and nearly impossible to fix due to the prior redaction of PII. This jeopardized the accuracy and success of the clinical trial. AI now offers the ability to automatically compare images collected at two timepoints, rather than compare patient names or ID numbers, to verify whether images depict the same individual. Doing this during the site upload process means errors can be detected before it's too late to fix them. This ensures patients' health trajectories are assessed accurately and saves sites and sponsors significant time.

Intelligent Clinical Keyword Search

At this point in the trial process, source materials are ready for clinical analysis. It's becoming increasingly common in drug and device trials for independent medical experts to evaluate clinical event information, particularly as endpoints become more diverse and are confounded by variables such as COVID-19. This process adds a layer of objectivity and expertise to the trial findings that the FDA values, but it can also be tedious given the manual nature and depth of clinical expertise required. AI technology can help at this juncture of the trial too.

Clinical adjudicators can receive anywhere from ten to hundreds of pages detailing a single clinical event for adjudication, depending on how much history the subject has. The adjudicator is charged with the critically important task of determining whether the clinical event is due to exposure to the drug or device being studied and must evaluate all source material provided to make an informed decision. The process includes carefully examining each page of source material for language pertinent to the event. Adjudicators are looking for a mix of medical conditions and procedures which vary depending on the trial. For example, a clinical adjudicator in a cardiac trial may be seeking evidence of a heart attack and may search for "myocardial infarction" in the source material. Once "myocardial infarction" is established as a clinical keyword, AI can be applied as a second set of eyes, highlighting that phrase every time it appears and directing the clinical expert to the most relevant sections.

Charles A. Powell, MD, MBA, is a seasoned clinical adjudicator. He said, "Thorough review of source material for relevant clinical context is core to my responsibility as a trusted adjudicator. It requires a high level of care because what I'm often looking for is a diagnosis of exclusion. I am mining a full clinical profile to surface the cause of, or explanation for, a specific clinical event. It can be a needle in a haystack. Having access to a tool that makes it easier to identify where those exclusions might exist and where I should focus my attention would make a big difference in how efficiently I can do my job." This assistive feature not only improves the workflow and saves time for busy adjudicators without sacrificing clinical integrity, but it also keeps costs in check for the sponsors who employ them.

Conclusion

There is no doubt AI's application in life sciences will continue to evolve, and its potential for enhancing the clinical trial process will likely expand as researchers become more comfortable with the technology. Increasing the ease and speed of clinical trial operations is a high priority for pharmaceutical companies looking to bring novel therapies to market as competently as possible. The evidence is clear that AI can play a strong supporting role in that endeavor, enabling new treatments to improve the lives of patients everywhere.

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