A Paradigm Shift in Patient Recruitment for Clinical Trials

White Paper

Accelerating Clinical Trial Patient Recruitment by Automating the Review of Clinical Narrative Using CNLP Technology

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Executive Summary

In the last two decades, technology has drastically changed how we conduct business and lead our personal lives.

Today, cell phones are used for more than just convenient ways to hold a conversation; daily recordings of both personal and professional lives are housed within a tiny, portable device. Within minutes you can look up a new place to eat, discover what previous diners have experienced, look at pictures of the food and ambience and get directions—all from a single device. However, medicine and more specifically the business of clinical trials hasn’t kept up. Finding patients for clinical trials, or patient recruitment, is still conducted very much as it was 20 years ago with very little having changed.
In addition to there being a lack of innovation in technology for patient recruitment, the complexity of recruitment has increased. It has long been known as the bottleneck of the approval process. Only 30% of patients that sign up for a study complete it to the end. This has significant impact on the credibility of the data required for approvals. This White Paper introduces a new technology for automating the pre-screening process for finding highly eligible patients matching clinical trial criteria delivering a paradigm shift in how patients can be identified - today.

QUICK STATS:

- **150% INCREASE** in number of eligibility criteria in the last 10 years
- **29% REDUCTION** in enrollment rates from 2013 to 2015
- **69% RETENTION RATE** in 2003 to just **30% in 2013**
- **30%+ OF PATIENTS REVIEWED REQUIRE MULTIPLE REVIEWS OF 30 MINUTES OR MORE**
- **$2 BILLION SPENT ANNUALLY** on just patient recruitment efforts and delays
- **NEARLY 100% OF TRIALS REQUIRE TIMELINE EXTENSIONS FOR RECRUITING ISSUES**

Community outreach, social media and advertising efforts spread the word about clinical trials, and help encourage patients to learn more about clinical trials, new treatments options and potentially create interest in participation. These are costly efforts with little to no return on overall recruitment outcomes. Structured or discrete-data searches can help to narrow down a large patient population pool to something a bit more manageable, but is rife with inaccurate, untimely and incomplete data. Knowing the pitfalls of the data and when to apply this strategy can be key to making things go more smoothly in the process. These current methods of recruiting patients work with good planning and strategy, but even then nearly all trials still require some type of extension for patient recruitment, which is costly. **It is estimated that up to 72% of patients that are eligible and eventually participate in clinical trials are part of the investigative sites patient population. It is just too time consuming and difficult to find them with current methods today.**

Manual chart review of a patient’s medical record is required regardless of how the patient learned about the study, and is typically how many of the eligible participants are identified. However, this process is burdensome, expensive and time intensive. The complexity of the eligibility criteria requires an appropriately skilled individual to review the information, so that clinical information is appropriately matched and interpreted. Failure to appropriately match criteria in this phase of the process can cause failures downstream and impact cost by increasing Screen Failure Rates (SFRs).

Isn’t it time that the business of clinical trials caught up with technology? Isn’t it time that there was a better way to identify that 72% of patients already within the investigative sites patient population without all of the time and effort of manual chart review?

Fortunately, there is by automating the process with Clinical Natural Language Processing (CNLP)-enabled technology. This new and innovative technology is causing a paradigm shift in pre-screening patients for clinical trial recruitment by finding qualified patients faster, more efficiently and more affordably via the unstructured clinical documents.
Clinical trials recruitment strategies haven’t changed much over the last two decades unlike almost everything else in our lives.

Can you remember a time when we managed without computers, cell phones, microwaves, email or GPS? A time when we wrote business correspondence by hand, cooked TV dinners in the oven, drove to the store to rent movies to watch at home and planned our driving route with a paper map?

Technology has transformed the world in which we live and work. It has changed the way we gather information, communicate, bank, shop, and travel. These changes have made us more productive, freeing us to use our time for more knowledge-oriented tasks. Technology is also transforming the clinical trial enterprise. In this White Paper, we look at how the clinical trial enterprise has found study participants over the last two decades, as well as an exciting new technology-enabled solution that is creating a paradigm shift in clinical trial recruitment and bringing the clinical trial enterprise into the digital age. This new technology can pre-screen thousands of patients against a trial’s eligibility criteria in a matter of hours.
Enrolling a sufficient number of patients in trials remains a chief bottleneck in the drug development process. Failure to achieve recruitment goals may jeopardize study quality by compromising study power and consuming study resources. As well, the temptation to broaden inclusion criteria could reduce the study’s validity. **Up to 45% of study delays of six months or more can be attributed to recruitment challenges.**<ref>(1)</ref>

Study protocol inclusion criteria have nearly doubled in the last decade, and overall complexity of study protocols has amplified. Due to safety concerns, eligibility criteria are carried over from earlier stages of the clinical trials phases are being included in later stage protocols. This dramatically increases the number of eligibility criteria that a patient must meet to be included in the study, further narrowing the patient pool. **Patient screening success rates have dipped as low as 23% in the past.**<ref>(3)</ref> Patient recruitment and pre-screening of patients can account for over 10% of the total budget for drug development.

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**Every month by which drug development process can be shortened is worth $25 million in revenue for the average sponsor.**<ref>(10)</ref>

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The Clinical Trials Transformation Initiative (CTTI) survey conducted in 2015 showed that finding or identifying patients who meet eligibility criteria, at 81%, was the most significant barrier to conducting clinical trials. The next most significant, at 67%, being insufficient staff time for recruitment tasks.<ref>(4)</ref> Research shows that these recruitment difficulties may lead to delays of one to six months for 86% of clinical trials, with the remaining 14% experiencing even longer delays. According to Centerwatch, 11% of investigational sites fail to recruit any patients and 37% under-recruit.<ref>(5)</ref>
The Costs Associated with Low Recruitment is Very Real

Clinical trial sponsors have noticed a significant increase in budgets and cost of delays. They may lose up to $1.3 million per day that a clinical trial is delayed due to recruitment issues.(6) Patient recruitment comprises one-third of the cost to clinical trial budgets. From 2008 to 2013, phase I trial budgets have risen 157% to $23,600 per patient enrolled. Phase II trial budgets have risen 108% in that same time period.

Investigational sites are not immune either. Because of the complexity of the eligibility criteria, much of the work to recruit patients requires a more skilled resource, such as an experienced clinical research nurse (CRN) or even a physician. This is especially true for oncology and rare disease trials. These resources conduct approximately 80% of the work to recruit patients into a trial, adding to the overall expense of conducting these trials.(8) Staffing of investigational sites can be around 40-45% of the total site budget with a dedicated staff of nurses, the principal investigator (PI), and clinical research associates (CRAs) among others. Investigational sites have seen an increase of 10% for study budgets in the last few years. And while this may not seem like a significant amount, when combined with low

Many veteran sites in the U.S. have been struggling financially in recent years, forcing some to shift resources to more profitable enterprises or even cease their clinical research altogether.(3)

enrollment rates, many sites are opting out of clinical research as a result.(9) The escalating costs associated with recruitment intricacies, regulatory expectations and other operational challenges leaves the impression of an industry struggling with fragmentation and inefficiencies.(9)
Methods For Finding Eligible Patients

The process of finding patients for pre-screening has been, and continues to be, long, laborious and expensive.

Traditionally, investigational sites use recruiting methods such as advertising, community outreach and structured data searches to generate a list of potential patients to enroll in a trial. Once a list of patients is generated, research staff still must conduct a manual medical record review to ensure these patients are pre-screened, or those who most likely meet complex inclusion and exclusion protocol criteria. These pre-screened patients are then invited to visit the clinic for additional screening and consent process. Given that so many studies fail to recruit as per plan, providing additional support to sites to help identify suitable patients during the critical pre-screening phase.

How successful are these decades-old “tried and true” recruitment strategies? An evaluation of published literature shows mixed results for activities such as advertising media (i.e. television, radio and newspaper), physician referrals, press releases, fliers, random mailings, cold calls and Internet-based activities. When the study criteria are broad and the intervention is low-risk, traditional outreach works quite well. However, these methods usually fail to bring in eligible patients for trials with complex inclusion and exclusion criteria, such as trials for rare disorders and oncology.

Limitations of Advertising and Outreach

Advertising and outreach to community members are common methods for attempting to find patients for clinical trials.

Community outreach involves finding eligible patients through patient groups, physician partners and other activities. The U.S. healthcare system is not one to encourage clinical research, as it can be risky, costly and time consuming, focusing instead on patient compliance and education, efficiency and profitability. All this and the ever-changing regulatory environment leaves little time for physicians to give attention to referring even the most eligible patients to clinical trials. Referring physicians must be educated and constantly reminded about the study particulars, such as eligibility criteria and procedures required for participation. Especially since in “...many instances, the characteristics of the study population, their comorbidities and therapeutic regimens, and the setting and conditions under which the trial is conducted bear little resemblance to typical community practice. Indeed, the outcomes are often quite different as well. It is little wonder that community physicians may be hesitant to modify their treatment practices to reflect clinical findings developed in this manner.”(11) In addition, physicians often have to refer patients away from their care for the duration of the clinical trial, resulting in a loss of revenue to their practice.
Partnering with patient groups, such as chronic or rare disease patient groups (Multiple Sclerosis Foundation, Lupus Foundation of America and the American Cancer Society), can be an effective way to recruit and educate patients. Patient groups are engaged advocates for their disease with loyal and active communities. Often patient groups are also involved in the development of treatment guidelines and pathways. It is an easy and valuable way to reach millions of patients and online communities. It is also proven to increase patient adherence and retention, as well as improve the probability of technical and regulatory success.

Other methods of community outreach involve advertising with posters, newspaper and radio ads and other forms of media including social media (Facebook and Twitter). A review of published literature on the impact of outreach and advertising shows a varied and unpredictable outcome with these established and well used methods. Social media, being the newest outreach method, can increase response to recruitment and enrollment by up to 78% with results of up to twelve times as many patients for studies with broad eligibility requirements.

Costs and Outcomes

In a study conducted at Beth Israel Deaconess Medical Center and Harvard Medical School, researchers evaluated the cost-effectiveness of different community outreach recruitment methods—multi-media advertisement, broadcast commercials, fliers and physician referrals—to recruit 289 patients into a clinical trial. Recruitment, anticipated to take four months, took 26 months, with low overall enrollment impact from the outreach and a higher than anticipated cost. Another study showed that out of 320 calls from a newspaper advertisement only 15 patients were randomized into the clinical trial. That is just under 5% of the calls resulting in an eligible patient. The average cost per randomized patient was over $3,000. Further analysis of recruitment trends of that trial showed that newspaper ads actually provided no overarching impact on increasing recruitment for that trial.

While it is true that 72% of patients are enrolled directly from the healthcare system's own patients, the effort, time and resources required to identify and recruit that 72% is quite onerous making the outreach and advertising aspects enticing means of attracting additional patients. While responses to traditional advertising and outreach are unpredictable; they do help create awareness of clinical trials and educate a broad population base. Understanding when and how to best utilize these strategies can be critical and necessary to a study’s overall recruitment strategy.
Misleading Information Conundrum in the Discrete-data

Structured data can help you narrow down a large pool of patients, but don’t let it artificially confine it or lead to patients that aren’t truly a good match.

Today, most trial enrollment strategies include search of discrete or structured data stored in data warehouses or Electronic Medical Records (EMRs). This structured data includes demographic, clinical laboratory and medication information combined with International Classification of Diseases (ICD) and CPT (Current Procedural Terminology) reimbursement codes. While automated data extraction from EMRs has augmented the process of finding eligible patients, many suffer from poor and incomplete data. Therefore, structured data search can lead to missed opportunities for finding patients. According to a 2013 Industry Standard Research (ISR) survey, only 13% of sites felt that EMRs had greatly increased the ability to identify patients.\(^{16}\)

Cost of Misleading Coding Errors

Inaccurate or incomplete coding occurs for several reasons, foremost of which is that coding systems in the U.S. are used primarily for revenue cycle purposes and not clinical practice.\(^{17}\) Only those codes most relevant to reimbursement are generally recorded in the structured data. Many codes that are relevant to determining clinical trial eligibility are not listed or simply do not exist. For example, there is no ICD code for clear surgical margins after tumor removal, a common exclusion criterion for oncology trials.

While conducting structured data searches have a relatively low-cost price tag attached to it, it can cost time and effort verifying the information. Much of what is written on the subject of today’s data describes it in a poor light and states that it wouldn’t stand up to the detailed analysis used to drive meaningful healthcare decisions.\(^{18}\) A recently published study compared automated review of structured data with manual chart to identify patients with Stage 3 Chronic Kidney Disease.\(^{17}\) (See image caption)

The study showed that 47% of patients thought to have Stage 3 kidney disease based on ICD-9 code, in fact did not have clinical indicators for that stage of the disease.
Unfortunately, structured data searches can artificially narrow the funnel of patients, missing patients that are, in fact, a good match for the trial when clinical narrative is reviewed. Conversely, discrete-data searches can lead to a patient pool that is riddled with inaccurate, incorrect or out of date information inflating the number of records requiring review. Supplementing a recruiting strategy with discreet data searches can be beneficial to identifying potential patients for a clinical trial. However, knowing how accurate, timely and complete the data available is, can be key to knowing when and how to optimize its use.

Burdens of Manual Chart Review

Even when all of the other avenues of patient recruitment have been successful, a chart review is still a necessary, critical step in the process.

Once a list of potentially eligible patients is obtained, research staff must review individual medical charts, narrowing down the list of potential patients to those most likely to meet the study’s inclusions and exclusion requirements. CRNs and Clinical Research Coordinators (CRCs), and in some cases PIs, must still comb through mountains of progress notes, discharge summaries, radiology and pathology reports and consultation notes to obtain viable, more dependable information to match the patient to the clinical trial study protocol. This information is called the unstructured data, or the free-form clinical narrative produced by clinicians treating the patient. Manual review of charts is an inefficient, labor and time intensive process, absorbing staff time that could be better used for engaging and retaining clinical trial participants. It also creates a significant financial burden for an institution. The numbers of eligible patients found with manual EMR review can be hopelessly low and eligibility poorly matched.

CHARACTERISTICS OF MANUAL REVIEW (8)
- High rate of screen failures
- Prone to human error
- Time and labor intensive
- Costs typically not reimbursed

OVER 80% OF THE RELEVANT PATIENT INFORMATION RESIDES WITHIN THE FREE-FORM CLINICAL NARRATIVE TEXT OF THE MEDICAL RECORD. MANUAL REVIEW IS TIME AND LABOR INTENSIVE.
Costs of Manual Screening
In a study at Virginia Commonwealth University, Massey Cancer Center, researchers evaluated overall and per patient costs for manual review of 3,467 completed patient evaluations for cancer trials over an 18-month period for 130 clinical trials. The total costs of the reviews were estimated at $90,505 annually for CRNs conducting the reviews versus CRCs. 

Over 32% of those patients required multiple reviews to assess eligibility, and 4.1% of those patients, or approximately 142 patients, required more than four reviews to evaluate eligibility. Approximately 2,000 patients required 30 or more minutes per review. That is more than 7,000 working days for just over half of the patients reviewed. According to the same study, many of these costs are not recuperated by the site. The costs of pre-screening patients for investigational sites can be 6.5% to 16.7% of the average total amount reimbursed per patient enrolled, with cost estimates from $120 to $2,508 per enrolled patient. Identifying eligible patients is one of the most challenging and crucial aspects of conducting clinical trials. Conducting a manual review of the information available is, currently, a burdensome, but necessary step within the process. It is laden with errors from misinterpretation, fatigue and clinical skill level mismatches. This critical step has more than one critical eye on its success/failure. The performance of all enrollment processes is measured in how quickly and efficiently investigational sites pull in patients for screening and consent.

CONDUCTING A MANUAL REVIEW OF THE INFORMATION AVAILABLE IS, CURRENTLY, A BURDENSOME, BUT NECESSARY STEP WITHIN THE PROCESS. IT IS LADEN WITH ERRORS FROM MISINTERPRETATION, FATIGUE AND CLINICAL SKILL LEVEL MISMATCHES.
The Trickle-down Effect for On-site Screening Failures

High Screening Failure Rates are said to be just the “cost of doing business,” but do they have to be?

On-site screening is the critical final step in the enrollment process before informed consent. Screening occurs when staff meet face-to-face with patients and may also include procedures, such as laboratory or other diagnostic testing, to ensure the patient currently meets all eligibility requirements. This vital step, however, has a high failure rate. In a study conducted reviewing over 27,000 patients screened over 172 sites, 95% were not enrolled.

What is the cause of high screen failures? Sites with low recruitment during the screening process may suffer from inadequately identified subjects or poorly matched patients from the manual review process, lack the required patient populations for study participation or have limited hours of availability for enrollment.\(^{(8)}\)

**Cost of Screen Failures Doesn’t Have to be the Cost of Doing Business**

Screen failure rates (SFRs) are measured in percentages, and the study budget is derived from an anticipated SFR. While SFRs can usually be fairly accurately predicted, when the processes and information feeding the screening have failed, those rates can continually be on the rise. While many screening tests and functions are reimbursed, it is at a fraction of the rate for a successfully enrolled patient. Many trials have a 32% screen failure rate, after the patient has been pre-qualified for the study. Even with a shared risk scenario, when recruitment numbers are down, screening unlikely subjects is a costly issue to both sponsors and sites.
A Paradigm Shift in Recruitment – Automated Pre-screening with CNLP

**Transforming the Future – Now**
Clinical trials recruitment strategies now have an innovative, cost-effective and powerful tool.

Sponsors, CROs, researchers and investigational sites still rely on the decades old methods to identify patients meeting the complex eligibility criteria of a clinical trial. However, just as technology has changed aspects of our personal and professional lives, today, there is another option that is both a time saving and cost saving tool – the computerized search of unstructured narrative data in electronic health records and digital platforms. More organizations are turning to CNLP (Clinical Natural Language Processing) to accelerate the slow, expensive and laborious process of finding highly eligible patients for clinical trials. CNLP is a paradigm shift for pre-screening patients for clinical trials, in that it is a new and innovative strategy that replaces the cumbersome and expensive manual chart reviews.
The Power of Automated Pre-screening with CNLP

Using CNLP, identifying existing patients in your health system’s data just got easier and faster.

Investigational sites, CROs and sponsors are turning to a powerful tool—once relegated to academia—that is transforming how participants are identified for clinical trials. CNLP automatically searches the unstructured narrative data in electronic files including clinical notes, radiology and pathology reports, and discharge summaries. Automating identification of eligible participants using CNLP to search unstructured data helps investigational sites find eligible patients that more closely match the complex inclusion and exclusion criteria of today’s clinical trial enterprise. CNLP is a technology-enabled solution that removes the need for extensive manual chart review almost entirely and identifies a larger cohort of high quality patients in a fraction of the time, releasing valuable staff time for other activities.

Origins of CNLP

Back in 2004, the NIH was interested in creating an informatics framework to understand complex genetic disease through examining large patient data sets.

They funded a center, named i2b2 (Informatics for Integrating Biology & the Bedside), at the Laboratory of Computer Science (LCS) at Harvard Medical School. The primary mission of the Center was to build an open-source platform that would analyze and extract content found in physician notes specific to areas of focus, such as smoking status, obesity and medications. While over 64 research organizations currently use the i2b2 platform to parse data from their own internal clinical data sets, this open-source platform requires skill and expertise most health systems do not currently have.

97% of respondents in the 2016 Validic Survey believe that digital technology will improve clinical trial cost effectiveness.
Build it or Buy it

cnlp can be an inexpensive and easy-to-use tool within the patient recruitment continuum, but creating one from scratch can be resource intensive and complicated.

Designing CNLP algorithms that read and interpret physicians’ natural language input is challenging because the software must be taught to understand and interpret complex medical terms, phrases, abbreviations and concepts. The greater sensitivity seen with CNLP is due in part to the differences between structured and unstructured data. While structured data categorizes patients by diagnoses, lab values, and medications, unstructured notes contain unorganized narrative that tells a story about the patient, their condition(s) and the resultant treatments. Acquiring the human and hardware resources to build an infrastructure to “machine read” clinical documents is costly and requires specific skill sets. Learning to program an NLP engine takes years of education and trial and error. NLP and, even more so, CNLP experts are difficult to find and lure away from current endeavors. Fortunately, organizations can license affordable, out-of-the-box ready solutions that read through clinical notes in a fraction of the time and more accurately than humans can. However, CNLP software solutions vary significantly in their functionality, ease of use and hardware requirements. It is essential to evaluate the CNLP platforms to ensure that the results and infrastructure meet the needs of the organization.
Automated Pre-screening vs. Manual Review

When comparing manual review to automated pre-screening of patients, the results make the decision simple.

Automating the pre-screening process of patients for clinical trials, or essentially allowing a computer to take over the time-consuming task of conducting the manual review of the medical records, streamlines the recruitment process. By utilizing CNLP in a way that transforms the previously unstructured clinical narrative into structured data that can then be queried for patients meeting the eligibility criteria, resources are freed up for other activities in the process. In the last few years as CNLP has been gaining recognition in healthcare, a few studies have been conducted proving that it is indeed a time-saving resource and can actually increase the accuracy of matching patients to trials.

In a study conducted at Cincinnati Children’s Hospital Medical Center, researchers compared automated eligibility screening via CNLP with manual review. The dataset for evaluation was based on 13 trials and 600 patient encounters. Researchers found that automated CNLP software significantly reduced physician workload, by 92%, while increasing the overall accuracy in which the patients were matched to the study criteria. In a retrospective study completed at the Icahn School of Medicine at Mount Sinai Hospital in New York, using automated eligibility screening via CNLP on a rare disease clinical trial proved to take ¼ of the time to find three times the number of patients that the research team identified. In just a matter of 30 minutes, the CNLP platform had read nearly 10,000 documents for over 500 patients.

450% increase in efficiency with automated CNLP unstructured search

Trial Site Workload reduced by more than 90% (19)

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<tr>
<th>Facility/Trial</th>
<th>Eligible Patients MANUAL</th>
<th>Time Elapsed MANUAL</th>
<th>Eligible Patients CLiX ENRICH</th>
<th>Time Elapsed CLiX ENRICH</th>
<th>Variance</th>
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<td>Mount Sinai – Diabetes/Kidney</td>
<td>7</td>
<td>4 months</td>
<td>97</td>
<td>2 Weeks</td>
<td>90 more patients in an ⅛ of the time</td>
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<tr>
<td>Mount Sinai – Rare Disease</td>
<td>3</td>
<td>9 Months</td>
<td>8</td>
<td>2 Weeks</td>
<td>5 more patients in just 2 weeks</td>
</tr>
<tr>
<td>ABMU – Diabetes/+Other</td>
<td>110</td>
<td>30 Weeks</td>
<td>541</td>
<td>4 Weeks</td>
<td>431 more patients in an ⅛ of the time</td>
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CNLP for Feasibility and Site Selection

CNLP can be a useful tool for feasibility and drive informed decisions during the site selection process.

As many as 60% of protocols require amendments. These amendments to the protocol can be driven by the need to relax the eligibility criteria due to a lack of patients meeting them. This causes more delays and can cost upwards of $500,000 to implement. These issues can be addressed using a combination of technological improvements, including CNLP, to make data-driven decisions about feasibility and site selection.

Early examination of the feasibility of a trial’s study design helps avoid trial delays and cost overruns. The more accurate the estimate of the feasibility of the study and patients meeting the trial criteria, the more smoothly the study will go while avoiding many of the initial challenges. Using CNLP technology, draft and final protocols can be quickly compared to large patient populations in geographic regions for sample size estimation, revision requirements and site selection. CNLP can also be used to expand the pool of potentially eligible patients in close proximity to known investigational sites. This could significantly reduce the expensive time delays associated with site selection and start up, decrease protocol amendments and minimize the need for rescue efforts.

The arduous task of selecting sites is key to the success of a study. Site selection can impact patient recruitment and retention, study timelines and budgets, and ultimately, the quality and reliability of the study data. Even with the best planning and information available about a study site, having the appropriate patient population available is critical to the success of selecting sites for a clinical trial. Inaccurate estimates in the total population and yield of participants from investigational sites and recruitment sources can lead to costly timeline extensions and even trial failures.

By using CNLP, in addition to other site selection strategies, both investigational sites and study sponsors can quickly determine the quality and quantity of eligible patients in a particular geographic region. Investigational sites can use CNLP to compare available patient populations to eligibility criteria to identify the number of patients, and more importantly, how well matched those patients are to the criteria. Not only can the sites report back to the study sponsors unbiased information about their populations, early indicators to which eligibility criteria will be potential barriers to recruitment can be identified.

“If you select a wrong site you will most probably not reach your goals and you will end up with delays and higher, unplanned costs.” (22)

—Marta Rayo Lunar, Project Manager, Advancell
CLiX ENRICH from Clinithink – the CNLP Leader

CLiX the ENRICHed difference

CLiX ENRICH for Clinical Trials is Clinithink’s breakthrough solution for accelerating clinical trial patient recruitment by automating the review of clinical narrative in the electronic patient records. The use of CNLP technology is creating a paradigm shift in the way investigative sites are finding patients for clinical trials throughout their organization – irrespective of the therapeutic area including oncology, endocrinology, rare disease, etc. In a study with the Icahn School of Medicine at Mount Sinai in New York, 10X more patients were found using CLiX ENRICH in ¼ of the time than what they could find using current methods of physician memory, manual chart review and structured ICD code search. That’s a game changer!

How does it work?
Clinithink has made the use of CNLP technology easy by developing a user friendly interface and workflow tool for clinicians, administrators and other staff as well as interfacing with other internal systems. CLiX ENRICH searches and interprets almost any electronically readable documents stored in your data warehouse, EMRs and other document storage systems truly unlocking the full potential of your data. It structures the unstructured (free text) narrative written in discharge summaries, physician notes, pathology and radiology reports, etc. Then, it queries the results using the clinical trial inclusion and exclusion criteria to find the highest quality candidates for your clinical trial. This “ENRICHed List” can then be used to enroll patients into the trial. CLiX ENRICH software resides on client servers or in the cloud – either way, patient health information can only be viewed by your own research staff.

Automated CNLP search is transforming the clinical trial enterprise, retooling the way highly eligible patients are identified for randomized clinical trials. Like many technological advances, there will be early and late adopters. Which one are you?

To discover how you too can accelerate patient recruitment with the information hidden in your free text documents email info@clinithink.com or visit clinithink.com
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