InSite

Case Study

Streamlining patient recruitment using EHR data

Patient recruitment: a bottleneck for clinical development

The field of (bio)pharmaceutical research is booming. Increasingly more innovative therapeutics are being developed with the ability to drastically improve the quality of life of millions of patients around the world. Rigorously testing each of these candidate drugs for their safety and efficacy is an essential part of the development process. As the number of clinical trials steadily increases, the search for patients who present a specific medical profile and are willing to participate intensifies.

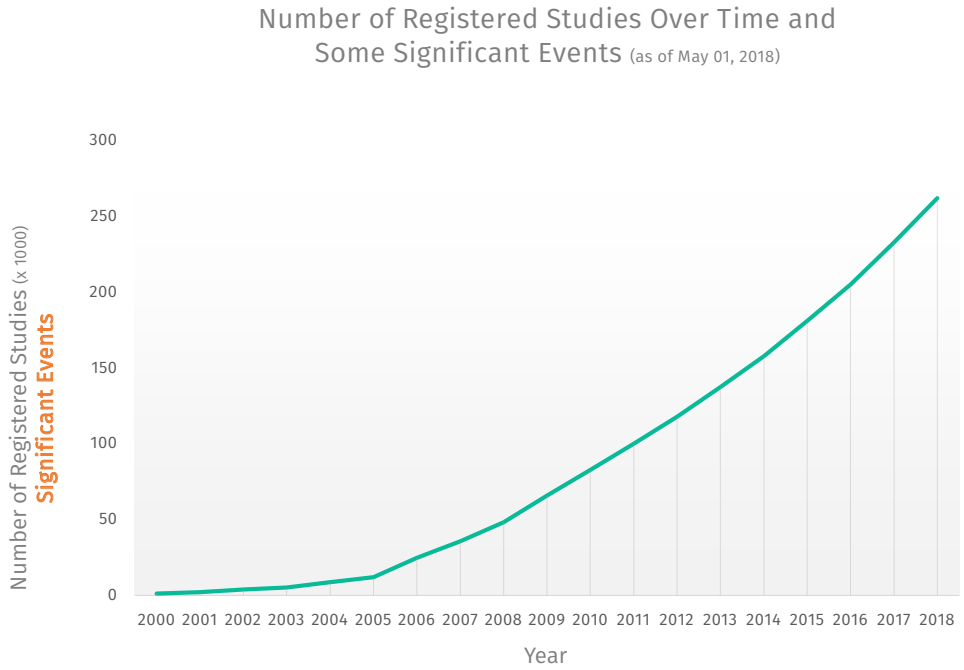

Figure 1: The number of clinical trials steadily increases (1)

80% of trials fail to recruit sufficient patients in time

20% of these trials are delayed for 6 months or more

66% of sites don't meet the enrollment targets

50% of sites enroll one or no patients

Patient recruitment is one of the primary bottlenecks in the clinical trial process. An estimated 65% of the R&D budget of pharmaceutical companies is allocated to clinical trials (2), representing a yearly multi-billion-dollar investment. Despite these allocated funds, 82% of EU trials fail to recruit sufficient patients in time (3), leading to delays that can exceed 6 months. Half of all trial delays are caused by patient recruitment problems (4). This is both detrimental from a business and an ethical perspective, as potential life-saving therapies reach the patient later, or sometimes never at all.

Despite these observations, the importance of timely patient recruitment is often overlooked. In a recent study (5), 47% of clinical development decision makers preferred 30% lower clinical trials costs over a 10% faster patient recruitment. While 30% savings in an average Phase II study correspond to $ 1.111 per day, companies lose up to $ 8.000.000 in sales for each day of delay in bringing a drug to the market. This makes it clear that optimizing patient recruitment should be a top priority in improving clinical research.

InSite improves upon the state-of-the-art

Patient recruitment is hampered by ineffective communication between sponsors and sites, and a lack of data-driven insight in the patient population. Study protocols are traditionally designed based on investigator experience and corrected with (costly) amendments if recruitment proves difficult. Site selection still relies on the cumbersome administrative process of feasibility questionnaires. These are completed by principal investigators at candidate sites, based on their view on the patient population and the data in patient records. This is a time-consuming and somewhat subjective methodology. In practice, over 2/3 of sites don't meet the enrollment targets that are subsequently set.

InSite helps all stakeholders in the process overcome these challenges and streamline their clinical research. InSite features the largest European network of innovative hospitals that lever their EHR data to increase their involvement in clinical research. Trial sponsors can use InSite to design better study protocols by testing the effect of inclusion and exclusion criteria on real-world patient data. Using InSite's free software suite, hospitals can request to participate in interesting trials and execute them more efficiently.

In the following cases, we demonstrate how InSite's computer-assisted patient identification module helps hospitals find eligible patients more efficiently. InSite allows investigators to better assess their recruitment potential before signing up for a trial and to speed up recruitment once they are participating. Overall, the risk of sites underperforming is reduced and delays minimised.

" InSite is a fast, powerful tool for the identification of eligible patients from our hospital records. With the software, we discovered 14 new patients who would otherwise have been missed, with the press of a button! "

Dr. Patricio Molero, Clínica Universidad de Navarra

Case 1: More eligible patients in a complex psychiatric trial

The Clínica Universidad de Navarra is a medium size university hospital in Pamplona (Spain), founded in 1962. The hospital is built around 50 medical departments and 10 specialized areas. As a non-profit university institution, the hospital complements patient care with teaching and research activities. In this regard, Dr. Patricio Molero Santos of the hospital's Psychiatry Department has participated in a trial aimed at testing the efficacy of esketamine, currently used as a general anesthetic, to reduce the symptoms of depression in patients who pose a high imminent risk for suicide.

Using the traditional patient recruitment methods, Dr. Molero succeeded in reaching the recruitment target of 4 patients within the first four months of the study. This proved nevertheless to be very challenging as the patients had to be in an unstable clinical situation, presenting an imminent risk of suicide. A fast screening method was thus essential to capture patients when they presented these symptoms, but before the standard therapeutic response was initiated, typically within a few days. A manual review of clinical charts proves too slow for this as patients are to be recruited in real time. With an automated method, patients could be targeted in advance, allowing the investigators to anticipate.

Most of the study's criteria could be formalized on the InSite platform allowing the entire patient database to be screened with the press of a button. From the electronic health records of 790.012 patients obtained in the past 10 years, 24 candidate patients were suggested by the InSite recruitment module in matter of minutes, including the previously identified patients for whom data was available to InSite.

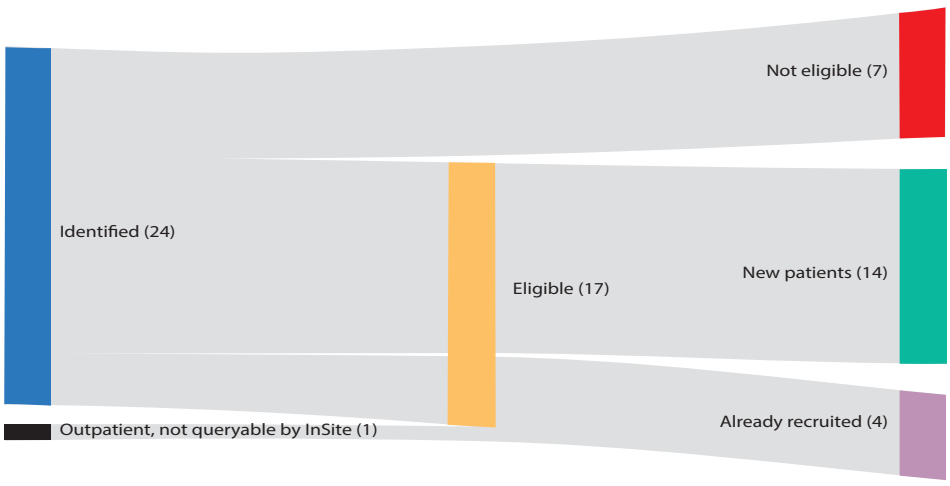

Figure 2: InSite's recruitment results at CUN

Individual verification of the 24 candidates revealed that **InSite successfully identified 17 eligible patients. This corresponds to a more than fourfold increase as 14 of these patients had been missed using the traditional approach.** Those patients were mainly overlooked because they were considered to be in remission and scheduled for distant follow-ups every few months. These consults are traditionally the only opportunity to detect a relapse that would make them eligible for the trial. In contrast, InSite was capable of identifying patients that had been treated by other departments, e.g. for a pneumonia, where a relapse of depression was recorded as a secondary diagnosis. Eligible patients could thus be identified instantaneously with InSite while they would only become visible in the traditional approach weeks or months later, at the time of their follow-up consult. Furthermore, some patients don't adhere to these follow-up appointments, making detection of depression as a secondary diagnosis even more important.

These remarkable results were obtained with a limited availability of patient data at the time of running this trial. Only patients with a hospitalization history were accessible to InSite when this comparison was made. In the future, outpatient records will be available as well, even more eligible patients will be identified (cf. 1 of the 4 patients initially identified manually was an outpatient). It demonstrates the importance of data quality and completeness, two aspects that are continuously optimized by InSite in collaboration with its partner hospitals.

Case 2: Faster patient identification in an oncology trial

The Instituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (IRST IRCCS) was founded in 2007 and is situated in Meldola, a small town in Emilia-Romagna (Italy). A network of interconnected medical services makes the IRST a center of excellence for cancer management and research. There are 36 inpatient beds for a total of over 21.000 patients per year, of them over 7.300 new patients.

" We got an overview of potential patients in hours instead of days."
Dr. Sara Testoni, I.R.S.T. Italy

In addition to cancer care, the IRST is also strongly involved in cancer research and the clinical development of new therapies. Thanks to the focus on a single disease area and the size of the hospital, the physicians are very well acquainted with the patient population. This makes identifying suitable candidates for upcoming trials more manageable than in larger hospitals. Nevertheless, even in this situation, a user-friendly platform that allows the principal investigator to query the information present in EHR records can provide a benefit in the recruitment process.

Dr. Sara Testoni, study coordinator for the uro-gynecological pathology group, and the team at the IRST have investigated how using the InSite platform could improve their workflow, by comparing InSite's performance to the traditional method of patient recruitment in an open trial.

The trial aimed to compare the short and long-term safety of a combination of immune checkpoint inhibitors with that of one of these compounds as a monotherapy. The study recruited patients with advanced solid malignancies, more specifically who were diagnosed with locally advanced or metastatic carcinoma of the urinary tract. Key eligibility criteria included that the patients had to have disease that has progressed during or after at least one previous chemotherapy to be eligible. However, they can not have been previously treated with these immune checkpoint inhibitors.

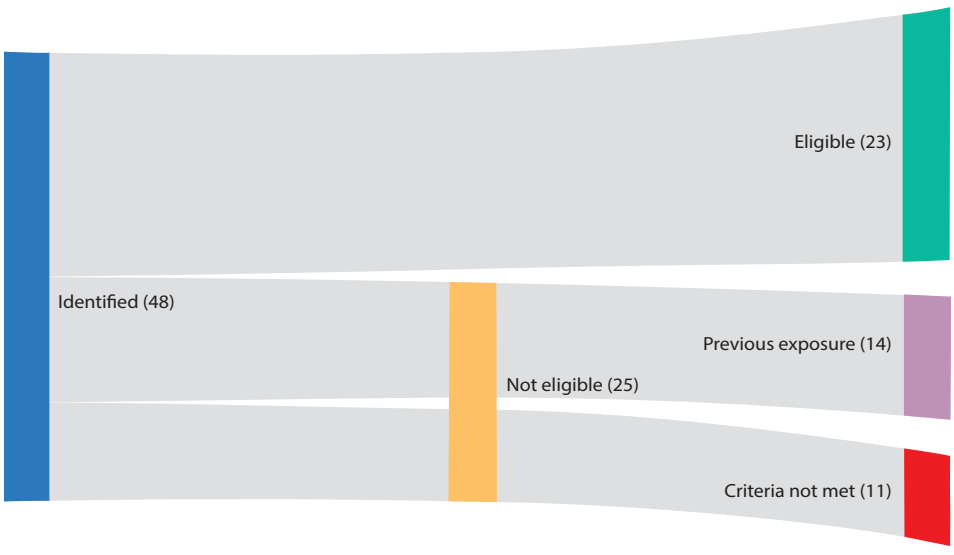

Figure 3: InSite's recruitment results at I.R.S.T.

From the total population of 71.600 patients, InSite suggested 48 potential candidates of which 23 were found to be eligible after manual verification. This corresponded exactly to the population that was found using the traditional approach, confirming InSite's accuracy and completeness. This traditional method already includes an initial query of EHR data. However, **with the InSite platform the same result was obtained with 2x less effort spent by the investigators (8 vs 16 hours).** This is a drastic improvement of an already highly optimized recruitment process, which can be attributed to an increased user friendliness and improved reporting allowing a faster screening. Using these tools, IRST outperformed other sites in the study with a five-fold higher recruitment.

The remaining 25 patients were found to be not eligible for the trial, of which 14 patients couldn't be recruited because they had already been exposed to immune checkpoint inhibitors (information at that point not yet available to InSite). Another 11 patients had to be excluded because of various clinical reasons.

Conclusion

Patient recruitment is one of the primary bottlenecks in the clinical trial process. Access for sponsors to real-world data in both study design and site selection facilitates patient recruitment and prevents the need for costly amendments. A deeper insight for hospitals in their patient data enables selecting interesting trials to participate in and identify more eligible patients in less time.

In this case study, we have demonstrated how InSite's computer-assisted patient identification tool supports hospitals in finding more eligible patients with higher efficiency (less resources spent). Using the InSite software suite, a single query from a large and diverse patient population found more than four times as many eligible patients in half the time for a complex psychiatric trial. Even in specialized hospitals where the patient population is very well known, InSite proved to be an accurate and complete solution that speeded up the recruitment process significantly.

Overall, the data-driven approach to patient recruitment demonstrated in this document prevents trial delays, bringing new drugs to patient faster and at a lower cost; to the benefit of clinicians, industry and above all patients.

more than 4 times as many patients in half the time

Sources:
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