White Paper

Finding All the Needles in the Haystack: Technology-Enabled Patient Identification for Clinical Trials

How using algorithm-assisted patient identification to improve recruitment in clinical trials can put research sites and trial sponsors ahead of the game.

MEIKE MADELUNG, Senior Consultant, EMEA Thought Leadership

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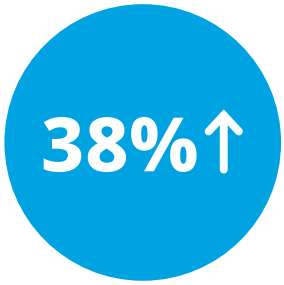
Introduction

In an ever more crowded clinical trial landscape with trial activity on the increase but trial performance dropping, finding the right patients to recruit as trial participants is becoming a major challenge, and one which many trial sites do not master, ultimately putting the trial success at risk.

For research sites and trial sponsors alike, patient recruitment is an activity that demands high resource commitments with an uncertain return.

Much effort goes into improving participant enrollment and retention rates, but a new approach is clearly needed.

This white paper sets out to investigate the current trial landscape as well as the barriers to patient enrollment and to lay out a technology-enabled approach to study feasibility and patient identification which promises to provide a fast and effective way of identifying the pool of eligible patients for primary care, specialty, and rare disease trials.



In 2021, the total number of trial participants exceeded 2 million for the first time. Nearly one million of these were for non-COVID-19-related trials, an increase of 38% over 2020.

The average likelihood of successfully completing all phases fell to 5% in 2021.

Source: Global Trends in R&D: Overview through 2021.
Report by the IQVIA Institute for Human Data Science.

Trends in clinical trial activity and performance:

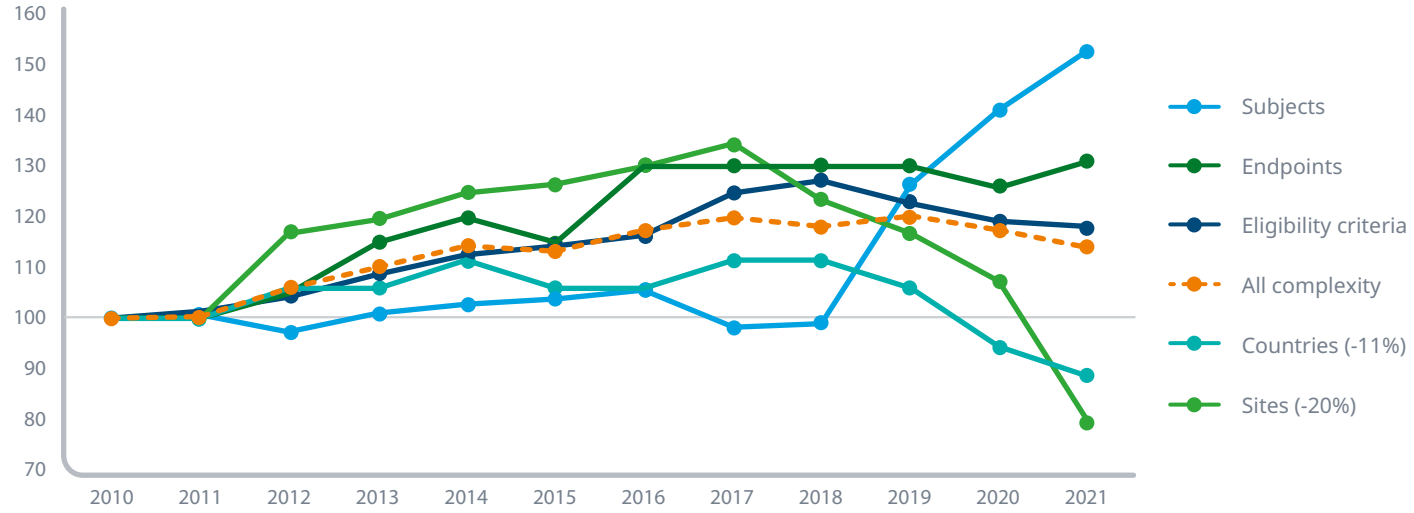
Although the COVID-19 pandemic resulted in a brief dip in trial activity, the overall number of active and scheduled clinical trials is on the increase globally, and the number of trial participants with it. According to a recent IQVIA Institute report[1], in 2021, the total number of trial participants exceeded 2 million for the first time. Nearly one million of these were for non-COVID-19-related trials, an increase of 38% over 2020. The report noted that at the same time, trial performance measured by productivity and success rates has decreased significantly over the last ten years. The average likelihood of successfully completing all phases fell to 5% in 2021.

A contributing factor to this drop in productivity is the increasing complexity of trials. The IQVIA Institute's analysis found an overall increase in the complexity from 2010 to 2019 driven by the number of subjects, endpoints, and eligibility criteria, although the latter have slightly decreased in complexity in the last two years, possibly due to the large-scale COVID-19 vaccine trials.

Although the COVID-19 pandemic resulted in a brief dip in trial activity, the overall number of active and scheduled clinical trials is on the increase globally, and the number of trial participants with it. According to a recent IQVIA Institute report,[1] in 2021, the total number of trial participants exceeded 2 million for the first time.

While the number of subjects has increased, there has been a trend towards geographic concentration. As the IQVIA Institute analysis shows, the number of countries and sites has decreased consistently since 2017.

Figure 1: Clinical trials' elements of complexity indexed to 2010 values, all phases



Source: Citeline Trialtrove, IQVIA Institute, Jan 2021.
Global Trends in R&D: Overview through 2021. Report by the IQVIA Institute for Human Data Science.

A more pronounced decrease in in 2020 and 2021 can be attributed to the COVID-19 pandemic and can be expected to reverse to a certain degree. As a result, the majority of clinical trials are concentrated in just a few countries. According to a new IQVIA white paper on the location of clinical development investment, in 2021, the US, Europe, Japan, and China hosted 73% of clinical trials while accounting for 86% of global pharmaceutical sales. Essentially, pharmaceutical companies situate a considerable proportion of their trials in their primary commercial markets.[2] However, this high concentration can lead to competition for trial sites and subjects, with demand in some indications exceeding the limits of capacity.

PATIENT UNDER-ENROLLMENT AS A SIGNIFICANT FACTOR IN TRIAL PERFORMANCE

A significant percentage of clinical trials fail to enroll the originally anticipated patient numbers or patient enrollment lags behind schedule, leading to longer trial durations and therefore longer time to market. One study identified a third of studies as low enrolling.[3] Significant under-enrollment can also adversely affect the scientific benefit from a study or result in modifications to the study protocol. Trials may end up insufficiently powered for statistical significance, or the eligibility criteria may have to be adjusted to be able to include enough patients to avoid this effect.

In interviews with leading industry representatives, timely and sufficient patient recruitment was identified as a main obstacle to successful trial activity, along with a concern that any delays would engender considerable additional costs.[4] Delayed time to market not only means immediate loss or delay of revenue against forecast, but also shorter overall time in the market before loss of exclusivity. Especially in therapy areas with intense R&D activity, where it is not unusual for several new therapies to be launched in quick succession, each month's delay may mean significant revenue loss over the product's lifetime since the product may not have sufficient time to be established with HCPs before the competition enters the market or may end up as a latecomer to the market itself. This is for instance the case in the PD-(L)1

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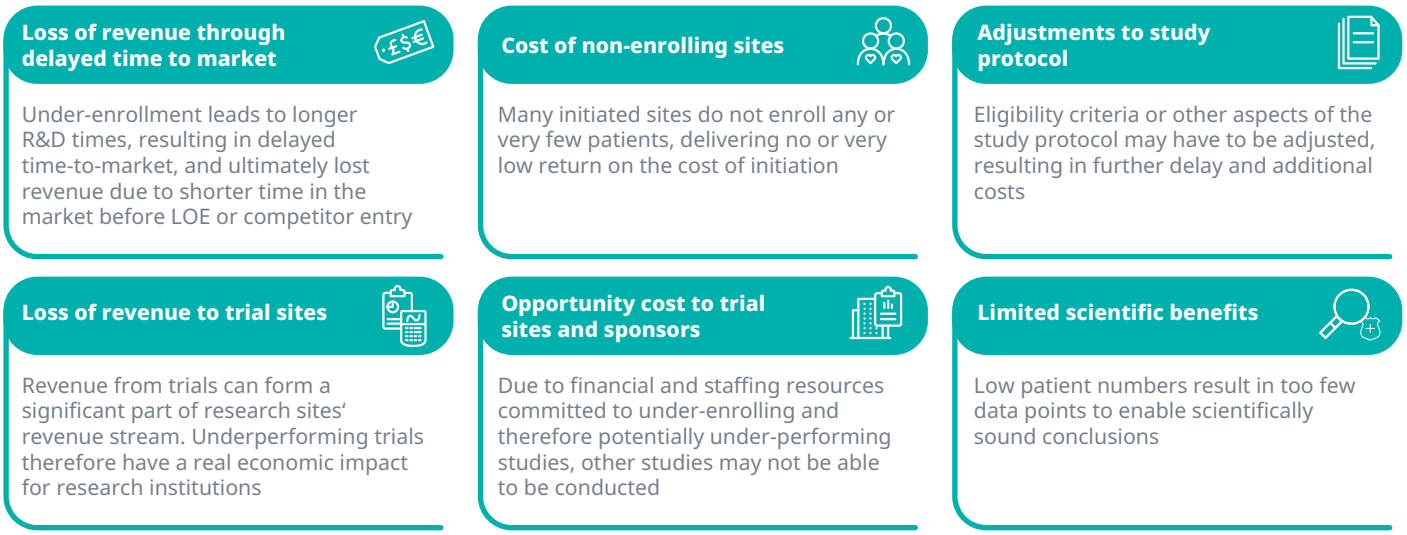
inhibitors market which is still dominated by the early entrants Keytruda and Opdivo and poses significant challenges to latecomers.[5]

There are also direct costs associated with low enrollment. A high percentage of trial sites end up being initiated but never recruit any or only very few trial participants. Industry sources speaking to IQVIA estimate the number of non-recruiting sites for the neurological sector at 25%, with an approximate cost of 80,000€ associated with each non-recruiting site.

The economic impact to trial sites is also significant since income from trials can make up a significant portion of a site's revenue stream. For Vall d'Hebron in Barcelona, a leading research hospital, revenue from trials accounted for 18.5% of its income in 2020.[6] For the Berlin Charité, third-party funds for research purposes of 196m € in 2020 represented just under 10% of its overall revenue stream[7] although this covers all research areas, not just clinical trials. There is therefore a direct, although difficult to quantify, economic cost to trial sites associated with under-enrolling studies but there is also an indirect opportunity cost, especially given that the health care sector in general struggles with resource limitations, both financially and in terms of staffing. Under-enrolling studies may not only yield very limited scientific benefits for the associated costs but due to the resources committed may prevent other studies from being conducted.[8]

Both industry sponsors and trial sites therefore have a vested interest in optimizing patient enrollment.

Figure 2: Impact of low enrollment



Source: IQVIA EMEA Thought Leadership.

FACTORS CONTRIBUTING TO LOW ENROLLMENT

As outlined above, the higher demand for trial participants caused by increasing trial activity coupled with more complex inclusion and exclusion criteria constitutes a significant challenge for the patient enrollment process.

Also contributing to greater complexity in inclusion and exclusion criteria are diversity requirements. Analyses for US-based trials have shown that alignment of race and ethnicity in the trial population with the disease-specific demographic epidemiology remains a challenge, with Asian patients often overrepresented and Black and Hispanic patients frequently underrepresented.[9] Adequate representation by gender can also be a problem. For other geographies, the situation will vary depending on population make-up, but similar issues are likely to be encountered.

Greater geographic concentration of clinical trials both in terms of countries and trial sites further increases the pressure on the patient identification and enrollment process. Trial sponsors are competing for a limited patient pool for their trials, a situation that is further exacerbated by the fact that large research centers will often run multiple trials focused on one indication. In addition, in the US, Europe and Japan, access to diagnosis and treatment is usually very good compared to other parts of the world, narrowing the pool of untreated or under-treated patients further. As a result, for some indications finding enough eligible patients can quickly become a challenge. At the same time, the US, UK, EU4, Japan and China are considered by many industry decision makers "cornerstone" countries for situating trials due to their commercial strategic importance, a recent IQVIA white paper found.[10] Improving enrollment rates in these countries with their highly saturated clinical trial environment is therefore crucial.

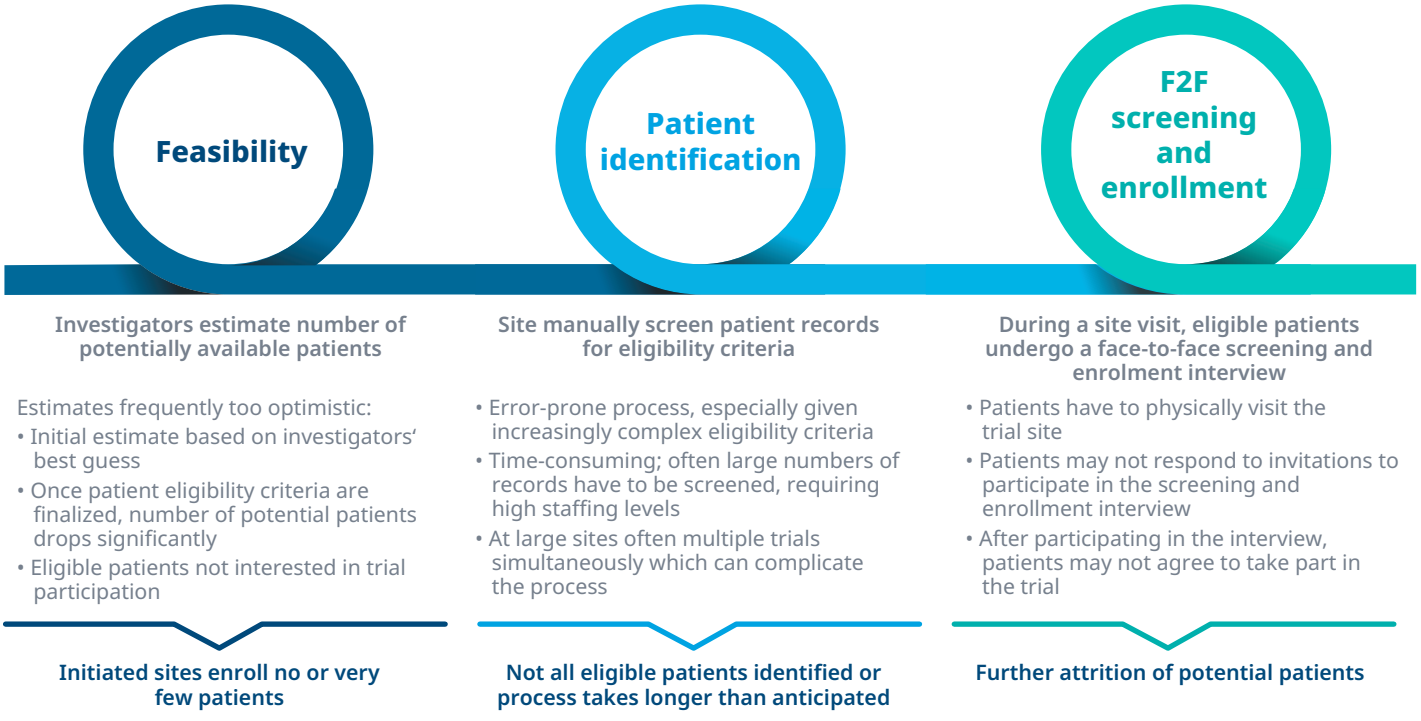
The higher demand for trial participants caused by increasing trial activity coupled with more complex inclusion and exclusion criteria constitutes a significant challenge for the patient enrollment process.

Studies of low enrollment largely focus on barriers to enrolling eligible patients, with little attention given to the process of identifying these patients in the first place. For instance, a review of strategies to improve patient recruitment evaluated interventions aimed at trial participants or at staff recruiting participants to improve enrollment.[11]

Another study on barriers to patient enrollment in cancer clinical trials interviewed clinicians and pharmaceutical industry representatives. Among the findings are that lack of awareness of both patients and physicians contribute to low enrollment, but also the increasing administrative burden both before study participation is agreed on as well as during the study. In addition, a trust gap between study sponsors and investigators has been noted, caused by some sites' incorrect estimate of suitable patients and subsequent failure to meet expected participant numbers.[12] This suggests that patient enrollment could be improved by more reliable identification during the feasibility stage of a study as well as process improvements that minimize the administrative burden for investigators.

A further factor, noted in a study on recruiting non-hospitalized patients to a COVID-19 trial in the United States, was lack of physician time to support trial activities, in addition to the challenges posed by the rapidly changing pandemic landscape.[13] Given that the standard process involves manual review of patient charts to determine eligibility, it is safe to assume that staff availability constraints play a role even in non-pandemic times. This is true for primary care, specialty care, and rare disease trials — for the former, usually large patient numbers are required, for the latter, the challenge may be finding any patients at all. Since specialty and rare diseases constitute a significant share of clinical trials overall, this is a particularly relevant challenge. At the end of 2021, 30% of the overall development pipeline were accounted for by rare diseases and of the 1,828 products in development, 216 were in phase III and 408 in phase II.[14]

Figure 3: Patient recruitment challenges



Source: IQVIA EMEA Thought Leadership.

INCREASING THE POOL OF POTENTIAL TRIAL PARTICIPANTS

While under-enrollment is widely seen as a risk to successful and timely development of innovative medicines, the focus of the discussion must widen to consider not only the recruitment and retention phases but also feasibility and identification of eligible patients. There is attrition throughout all stages of the process but improving speed and accuracy of estimates of available patients during feasibility as well as the identification of eligible patients once inclusion and exclusion criteria have been defined can be expected to provide a larger pool of patients to start with. A less time-consuming method of patient identification will also free up staff time to engage with eligible patients in person to focus on enrollment and retention.

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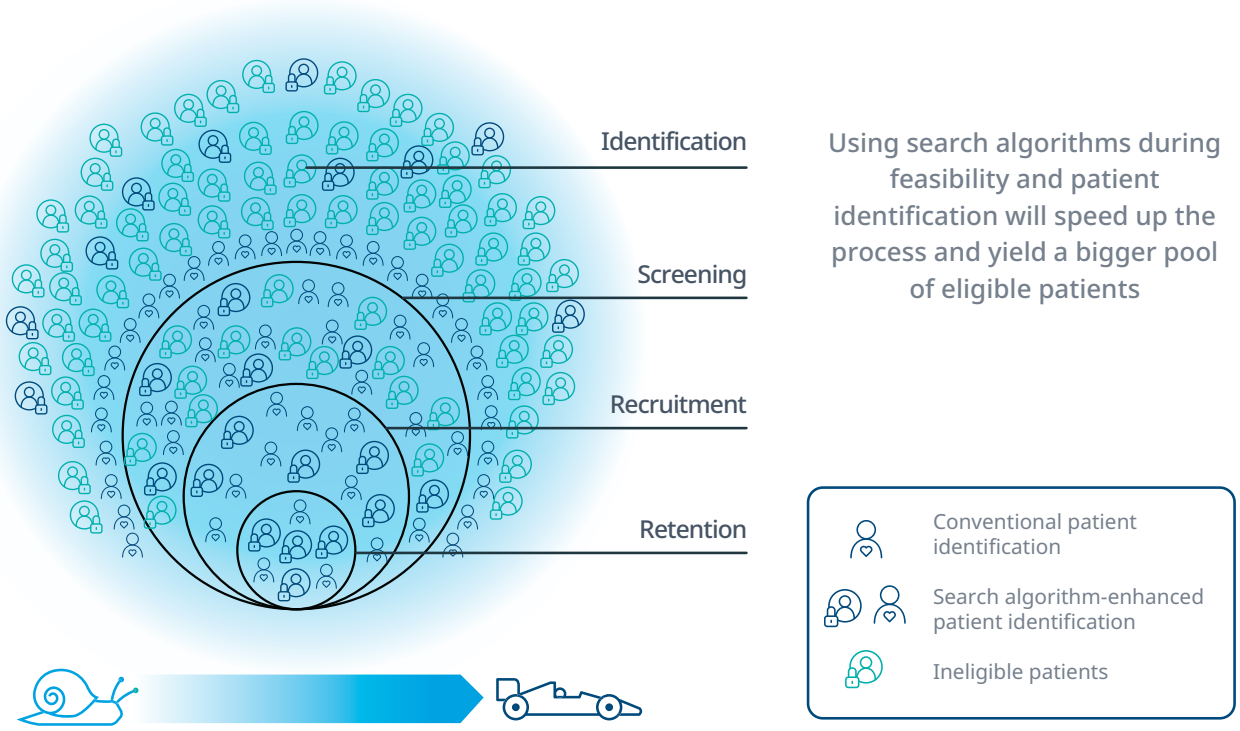
Figure 4: Using search algorithms to increase pool of eligible patients



Source: IQVIA EMEA Thought Leadership.

Query-driven search algorithms as a faster and more efficient method of patient identification

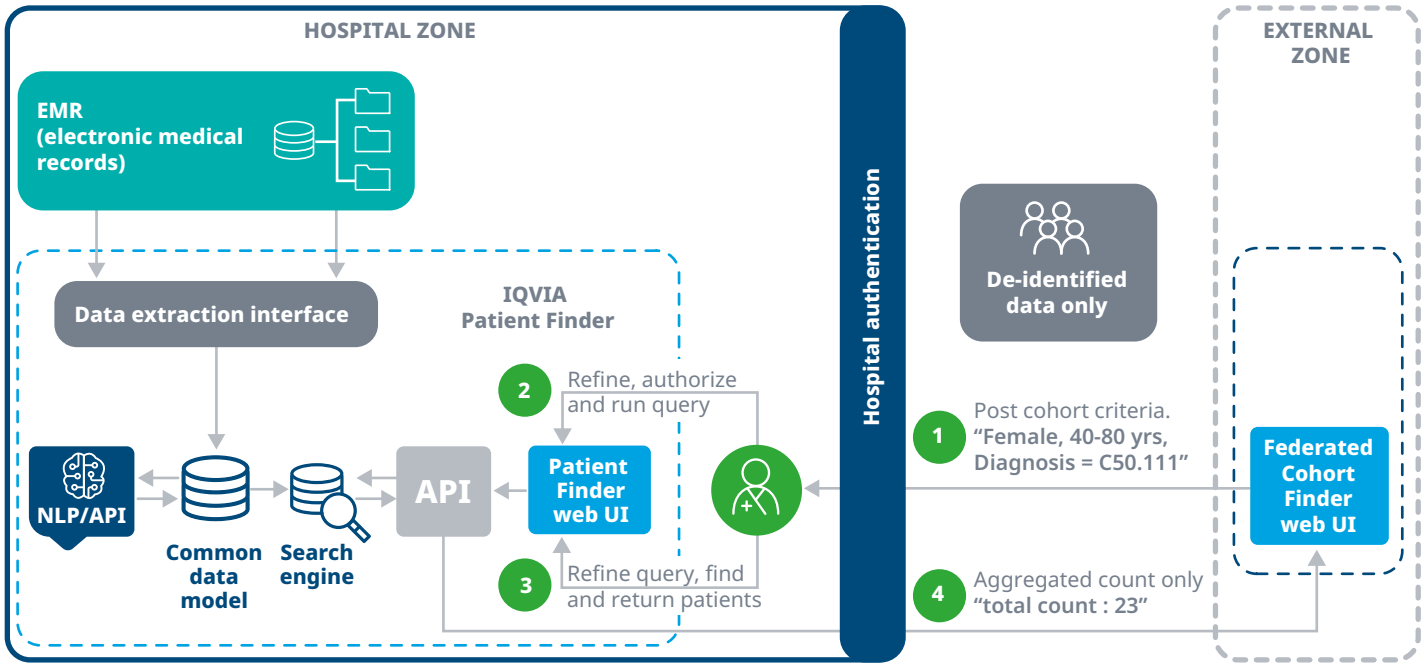
Using query-driven search algorithms to identify eligible patients relies on patients already being part of the healthcare ecosystem and an electronic healthcare record (EHR) being available. The approach requires specialized software which is installed in the trial site's IT environment and is then used to query both structured and unstructured data in the hospital's EHR. This ensures that sensitive patient information does not leave the hospital IT environment.

Relevant patient records are provided to investigators in a pseudonymized version to ensure compliance with data privacy regulations. Investigators can then review these records and select patients for screening and enrollment interviews. Eventually, an authorized HCP will work with the re-identified records in order to discuss potential study participation with the patients.

In a second step, once patients have been enrolled and given consent, relevant data points can be extracted from the EHR to a file or separate database and can be further processed from there. The automated data extraction results in considerable time savings compared to the current approach which usually requires manual data transfer or collecting the data again from scratch from the patient. Limiting the data export to relevant data points also ensures that the principle of data minimization is respected in accordance with relevant data privacy regulations.

The IQVIA Patient Finder software can be used as a stand-alone solution or in conjunction with the data extraction module and is compatible with leading EHR systems. It can also be combined with a data integration solution such as CentraXX as well as with a natural language processing (NLP) software to provide further analytical options.

Figure 5: IQVIA Patient Finder schematic



Source: IQVIA EMEA Thought Leadership.

RETROSPECTIVE COMPARISON OF ALGORITHM-ASSISTED SEARCH OF EHR DATA WITH MANUAL EHR REVIEW

In a direct comparison, a study has shown that using query-based algorithms to search EHR data yields high-quality results both in identifying eligible patients based on the information stored in the EHR and in extracting the relevant data points from the EHR.

For this study, a software enabling algorithm-assisted EHR searches (IQVIA Patient Finder) was programmed to screen the health records of patients who presented at selected medical centers during the recruitment period for a cardiovascular trial on the effects of colchicine in patients with stable coronary heart disease for the relevant indication as well as additional inclusion and exclusion criteria. In a second step, relevant data points were transferred from the EHR system to the clinical trial records. Both sets of results were then compared to the actual trial cohort and records.

Over 90,000 patient records were screened automatically in three different medical centers with different EHR systems installed. Over 18,000 patients, or 20%, were identified as eligible for inclusion. These patients would still have to be screened manually to verify eligibility. Of the 568 patients who were actually included in the trial, 82.4% were part of the group identified as eligible.[15] Due to the retrospective setup of the study, it is impossible to tell how many patients out of the group identified as eligible would have been included but it is fair to assume there would have been a not insignificant number of additional trial participants.

The data extracted automatically was largely correct compared to that entered manually into the clinical trial records. Some minor deviations were due to a criterion definition ("uses antihypertension drugs") that was difficult to translate into the text-mining query.

Assuming that all 90,000+ patients who visited the participating centers during the recruitment period for the trial were in fact screened for eligibility, with an estimated 5 minutes per patient, using automated screening to narrow down the number of patients to be screened manually by 80% already constitutes a significant time and resource saving. The query definition for both the EHR screening and data transfer took 25 hours, data extraction and upload for participating patients an estimated further five hours. Compared against an estimated 45 minutes per patient for the traditional manual screening and data transfer process, this constitutes a tremendous efficiency gain, especially given the high quality of the results.

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IDENTIFICATION OF PATIENTS AT RISK FOR ULTRA-RARE DISEASE

Algorithm-assisted search of EHR works not just for high-incidence indications like cardiovascular conditions, but also for rare and ultra-rare diseases. For transthyretin cardiac amyloidosis (ATTR-CA), a condition which in the US is estimated to have an incidence of 0.03% of the population, and is considered severely underdiagnosed, in a pilot study run by IQVIA algorithm-assisted EHR data mining was able to narrow down a pool of more than 100,000 patients to 22 patients likely to be at risk of the disease. These 22 patients were then further assessed by a cardiology team and one patient was eventually tested and diagnosed with the disease.[16]

Figure 6: Examples of employing query-based algorithms to search EHR data

	RETROSPECTIVE COMPARISON OF ALGORITHM-ASSISTED SEARCH OF EHR DATA WITH MANUAL EHR REVIEW	IDENTIFICATION OF HIGH-RISK PATIENTS FOR ULTRA-RARE DISEASE	OUTCOME RESEARCH IN METASTATIC RENAL CELL CARCINOMA	PREDICTORS OF CARDIAC REHABILITATION REFERRAL, ENROLLMENT, AND COMPLETION
Issue	Compare speed and quality of algorithm-assisted search of EHR data for patient identification and data transfer in clinical trials to the manual process.	Identify patients at risk of the ultra-rare disease transthyretin cardiac amyloidosis (ATTR-CA). A previous search across several countries had been unsuccessful.	Assess suitability of algorithm-assisted data mining (IQVIA Patient Finder) for evaluating outcomes in metastatic renal cell carcinoma.	Identify predictors for successful referral, enrolment, and completion of outpatient cardiac rehabilitation for patients with AMI (acute myocardial infarction).
Solution	Software enabling algorithm-assisted EHR searches (IQVIA Patient Finder) was programmed to screen the health records of patients who presented at selected medical centers during the recruitment period for a cardiovascular trial for the trial inclusion and exclusion criteria. In a second step, relevant data points were transferred from the EHR system to the clinical trial records. Both sets of results were then compared to the actual trial cohort and records.	Algorithm-assisted EHR data mining was used to screen a pool of than 100,000 patients to 22 patients likely to be at risk of the disease. One patient was eventually tested and diagnosed with the disease.	In a retrospective cohort study, patient records were screened both manually and using an automated text mining tool for inclusion criteria including diagnosis and treatments, and the relevant data, in particular outcome information like progression-free survival and overall survival from the resulting cohort were collected, again using manual and automated collection in direct comparison.	In a retrospective cohort study, IQVIA Patient Finder was used to extract baseline characteristics and data on CR referral, enrolment, and completion for a cohort of 666 patients. Data was analyzed to identify predictors of CR success.
Outcome	• > 90,000 patient records screened • 20% identified as eligible • Data for 458 patients was extracted and transferred • Of the 568 patients included in the trial, 458 (82.4%) were part of the group identified as eligible • Automated data transfer compared favourably to manually maintained records	• > 100,000 patient records screened • 22 patients identified as at risk • After further evaluation by a team of cardiology experts, one patient was eventually diagnosed	• 100 patients identified with a 99% match • 175 treatments identified, with 99.5% matching • high degree of overlap especially for primary outcomes like progression-free survival and overall survival • Mean time per patient 86 min for manual chart review, 12min for automated data collection	A number of distinct predictors for referral, enrollment, and completion could be identified, increasing chances of successfully rehabilitating patients and improving long-term survival.
Benefits	• Automated EHR screening constituted a time saving of app. 80% • Data transferal took 30hrs for all 458 patients compared to app. 45min per patient for manual extraction and transferal • Both screening results and data transferal were of high quality with little deviation to the results for the manual process	• Large numbers of patient records were screened with a high degree of accuracy • After four months, one patient was diagnosed	Algorithm-assisted data mining provided excellent results and considerable time savings	IQVIA Patient Finder provided a fast and efficient method of extracting necessary data points in the required quality.

Source: IQVIA EMEA Thought Leadership.

AUTOMATED COLLECTION OF RELEVANT DATA POINTS IN RENAL CELL CARCINOMA AND CARDIAC REHABILITATION

Similarly, a comparative study of the use of the automated search and extraction of relevant data points in the context of using real-world data for outcome research in metastatic renal cell carcinoma found the method to be both reliable and time-efficient.

In this retrospective cohort study, patient records at a medical treatment center were screened for inclusion criteria including diagnosis and treatments both manually and using a query-based search and extraction tool. The relevant data, in particular outcome information like progression-free survival and overall survival from the resulting cohort were collected, again using manual and automated collection in direct comparison.

Both methods identified 100 patients with a 99% match, and 175 treatments, where 174 treatments were identical. The differences were accounted for by discrepancies in the underlying EHR. Equally promising were the results for the collected outcome data with a high degree of overlap especially for primary outcomes like progression-free survival and overall survival.

A comparative study of the use of the automated search and extraction of relevant data points in the context of using real-world data for outcome research in metastatic renal cell carcinoma found the method to be both reliable and time-efficient.

The mean time per patient for manual chart review was 86 minutes versus 12 minutes for automated review and collection.[17]

The search algorithm software has also been used successfully to collect relevant data from electronic health records in a retrospective cohort study on predictors of cardiac rehabilitation referral and completion.[18]

Benefits of algorithm-assisted patient identification

Employing a query-based search algorithm for patient identification has been shown to have significant advantages in terms of reliability, efficiency, and cost effectiveness. Since the text-mining software is integrated with the hospital IT environment and search results are automatically de-identified, no sensitive patient data leaves the hospital EHR system. Since only relevant data points are picked up and if required extracted, it minimizes the use of sensitive data. The solution therefore can be considered fully compliant with relevant data privacy regulations.

The solution is EHR-agnostic and can be implemented within any hospital IT system, although it can also be integrated with data management solutions such as CentraXX.

Algorithm-assisted patient identification has been shown to work with primary care indications, specialty care, and rare diseases, and helps to create reliable selections based on complex inclusion and exclusion criteria as well as transfer relevant data points while requiring a fraction of the time investment for the traditional manual review and data transfer process.

Conclusion

Patient under-enrollment is highly prevalent in clinical trials and constitutes a major problem for R&D performance, putting development timelines at risk and generating considerable direct and indirect costs. This trend is driven by growing demand for trial participants due to increased trial activity especially in specialty and rare diseases, more and more complex inclusion and exclusion criteria, and concentration of trial activity in a few core countries.

If research institutions and trial sponsors do not want to fall behind in the race to bring new cures to patients, it is essential for them to revisit the entire recruitment process from feasibility to patient retention, increase the focus on the feasibility and patient identification stages, and employ novel, technology-assisted approaches to maximize speed and efficiency in identifying eligible patients and minimize demands on research budget and staff time.

Especially large research institutions with a complex ecosystem of multiple data repositories will benefit from employing this approach. To reap the maximum benefits, they should also consider implementing a fully integrated solution including an algorithm-powered patient identification and data extraction solution as well as a centralized data management system.

Trial sponsors and sites are also well advised to take the capabilities of the algorithm-assisted search into account during trial design and protocol definition and to employ the solution as early as the feasibility phase to minimize the number of low- or non-enrolling sites.

For research sites and trial sponsors to succeed in an increasingly competitive research landscape, they must embrace a novel approach to patient identification - now.

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About the author

MEIKE MADELUNG
Senior Consultant,
EMEA Thought Leadership,
IQVIA

Meike Madelung is a Senior Consultant with the EMEA Thought Leadership team and based in Frankfurt, Germany. She develops and presents insights and analyses on a range of key topics based on IQVIA's data assets and expertise. Areas of interest include clinical trial optimization, the immunology product landscape, and patient-level data.

Meike has been with IQVIA for over fifteen years in a variety of roles both in London, UK and in Frankfurt, Germany. She has expertise in RX and Consumer Health data and markets both at the national and international level.

Meike holds an MA from the University of Bonn, Germany and an MBA from Royal Holloway, University of London.

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