Using electronic health records and time-saving technologies to modernize clinical trials

In 2019, Optum approached three provider organizations about participating in a multicenter, prospective observational study.

The study had two objectives: 1) test new approaches for conducting clinical trials and 2) evaluate treatment patterns in patients with Type 2 diabetes who have less than ideal HbA1c levels on metformin only during routine clinical care.

Western Washington Medical Group in Washington, Wilmington Health in North Carolina (both part of the Innovo Research Network) and Reliant Medical Group in Massachusetts participated in the study. Stephanie Abbott, PharmD and director of research at Western Washington, said, "I'm always interested in finding new ways to improve clinical trials. I've worked in the field for many years and it's definitely ripe for positive disruption."

Tracy Ohrt, clinical operations manager and Cynthia Senerchia, vice president of data management and analytics, led the effort for Optum. "We've been working on ways to combine data and technology that accelerates the pace of trials, reduces overall cost and improves both the patient and provider experience," Ohrt explains. "We were anxious to put some of these new approaches to the test in the real world, so we appreciated all three health care providers' willingness to participate."

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— **Stephanie Abbott,** PharmD and director of research at Western Washington

About the study

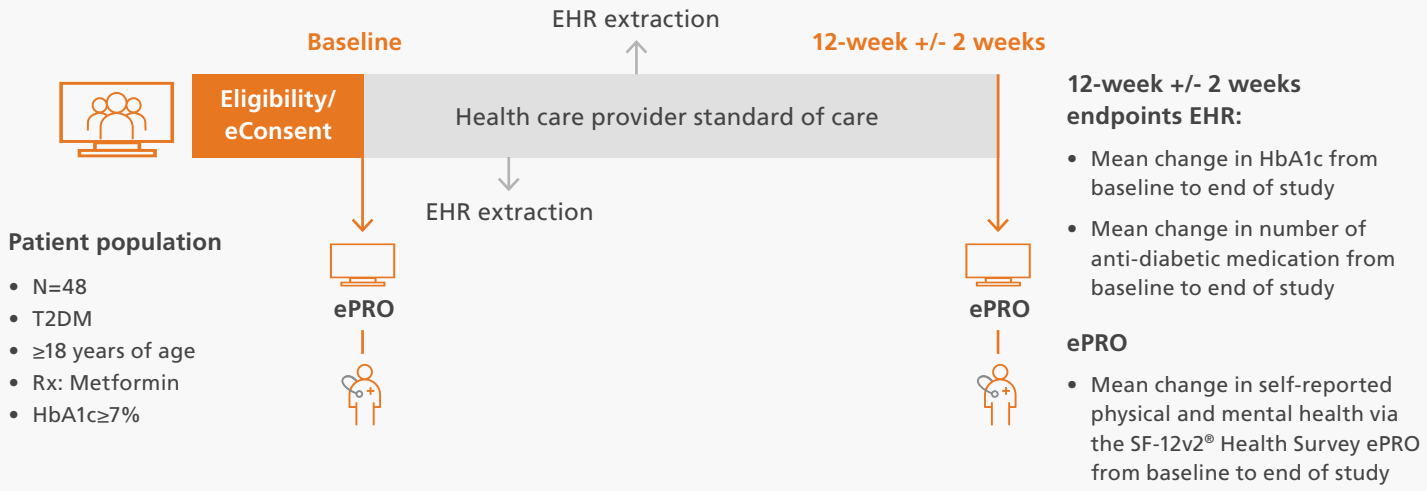
The study began in June 2020 and was completed in January 2021. A total of 48 patients enrolled, ages 18 years and older. All were taking metformin and had a HbA1c of greater than 7%. These patients were followed for a 12-week period with data relating to clinical care encounters and lab measurements collected via direct extraction from the sites' electronic health record (EHR) systems and evaluated. Patients were also administered an electronic patient reported outcome survey (SF-12v2®) at baseline and study end.

"We intentionally chose the three providers as they were spread out around the country and all three used different electronic health record systems," explained Ohrt. "This allowed us to test these new technologies and approaches in a way that reflected a real-world situation."

Figure 1 shows the study's conceptual model in more detail.

Figure 1

ePRO: Electronic Patient-Reported Outcome



Below are some of the initial findings from this innovative work.

Finding and recruiting patients

The facts are not surprising for anyone in the clinical trial field. Approximately 80% of drug clinical trials do not meet enrollment deadlines, which can result in average losses of up to $1.3 million a day. Similarly, 37% of research sites miss enrollment targets and 10% fail to even recruit a single patient. This is due in large part to eligibility criteria exploding in growth over the years. Between 2002 and 2013 for example, eligibility criteria grew by 61%.[1]

Research staff at these and other research sites typically spend hours combing through their records to find data that indicates a patient might be eligible to participate in a clinical trial. But for this study, site staff were provided lists of potentially eligible patients from the Optum team who leveraged their EHR data. By applying data algorithms using the inclusion and exclusion criteria to this database, thousands of medical records could be searched automatically, returning results in minutes rather than hours of manual searching.

During the recruitment phase, Optum supplied site staff with multiple lists of potentially eligible patients (10 lists in total). Each time a new list of patients was generated, Optum removed patients based on feedback from the sites and added new patients.

A feedback loop was established as part of the list generation and staff outreach process. Recruiters would evaluate possible participants and complete a log of the results. Optum would then remove patients deemed either ineligible or unwilling to participate before running a new list and adding new patients.

A significant reduction in prescreening effort resulted from the more automated approach to study eligibility.

Key findings:

- A significant reduction in prescreening effort resulted from this more automated approach. Manual patient finding efforts for an oncology study take **0.94 hours per patient.** In this study, average effort for each patient was just **three minutes,** and many hours of staff time were saved. See Figure 2 on the next page for more details.
- Based on an anonymous staff survey conducted at the end of the study, 86% of site staff indicated that they were extremely satisfied or satisfied with the accuracy of the patient lists provided.

"The ability to have patients essentially preselected for the study was so attractive for us," explained Brian Webster, MD, chief medical information officer at Wilmington Health. "Not having to do significant data queries or a lot of manual chart evaluation significantly shortened the prescreening process."

Data entry and staff burden

Health care providers are often eager to participate in clinical trials. It offers their patients a way to access the latest treatments and therapies. It also offers additional revenue streams for the practice. But providers are often overwhelmed by the paperwork and administrative burdens that come along with these opportunities. According to Frost & Sullivan's 2018 report,[1] 54% of investigators don't return to clinical research after their first trial. This is a concern for both trial sponsors and the broader health system.

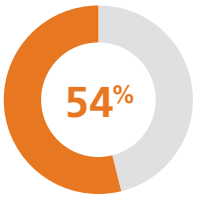


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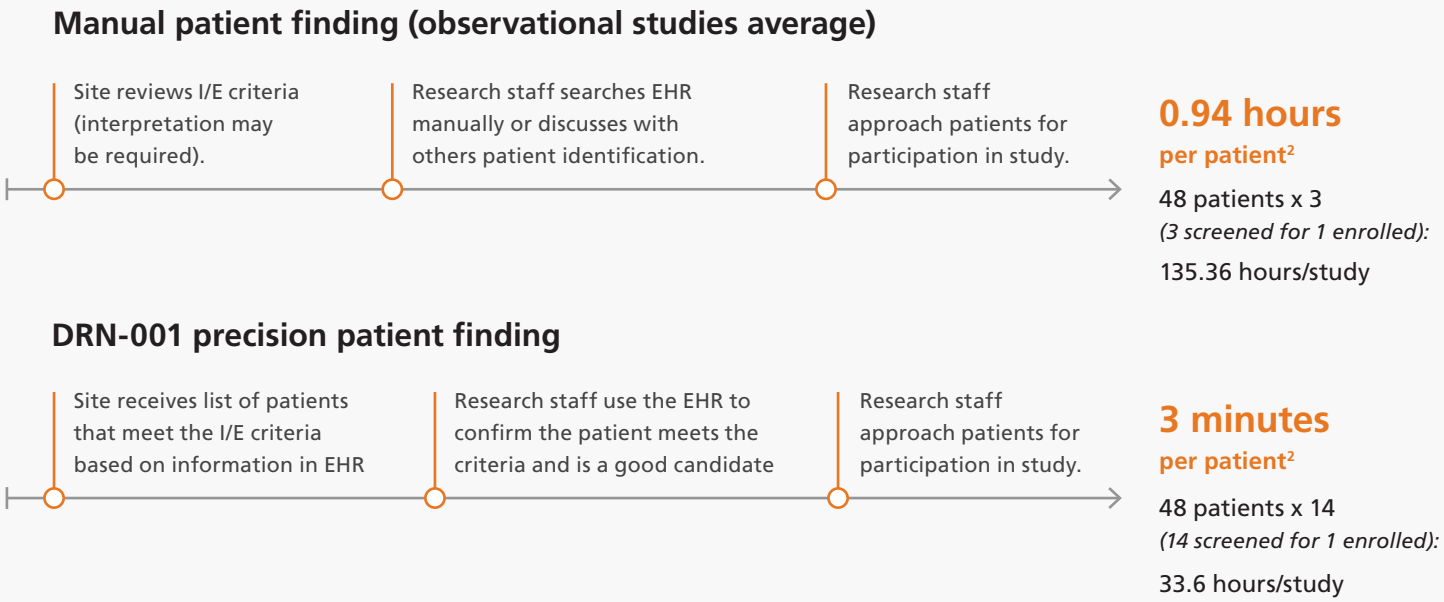
Figure 2



Optum developed a technology designed to address this problem. It's a type of middleware that enables the transfer of data from an EHR into an electronic data capture (EDC) system, eliminating much of the manual data entry normally required. Positioned between an operating system and the applications running on it, middleware software essentially functions as a hidden translation layer, enabling communication and data management for distributed applications.

In a typical study, a clinical care provider will enter relevant patient data into the EHR at the time the patient is seen. Then subsequently, the same data will be manually transcribed into the EDC system by a member of the research team. This process often results in transcription errors due to the study staff workload and competing priorities. For any study destined to support a regulatory decision, sponsors have an obligation to perform some source data verification (SDV) to ensure the data in the EDC match the data in the source (such as EHR).

This process is time-consuming and costly and can, according to some consultants, be responsible for as much as 30% of the budget for a given clinical trial. While post-approval studies do not have the same regulatory requirement for SDV, most sponsors will conduct SDV as part of their clinical monitoring to ensure adequate quality checks of the data. SDV is not necessary for this electronic-to-electronic transfer process as the source data — along with the metadata from the EHR — is directly loaded to the EDC, removing the need for additional effort and cost from SDV requirements.

Clearly, being able to pull the source data directly from EHR to EDC is more efficient. Larry Garber, MD, medical director for informatics at Reliant Medical Group, was pleasantly surprised by the accuracy of the data. "It was really spot on because it was essentially coming right from our EHR," said Dr. Garber.

As anyone who works with clinical data knows, this is not a simple copy-and-paste functionality, especially across three different EHR, as in this study. Different EHR systems capture the same data in different ways, dates, race, ethnicity and much more. We also encountered differences in how vital sign measurements are captured, different units of measure (pounds, ounces or kilograms for weight, inches or centimeters for height). Even how patient blood pressure is captured can differ — both systolic and diastolic in one field with a forward slash separator, or recorded in two separate fields.

The process of extracting, normalizing and curating this data requires the combination of deep health care experience and cutting-edge technology at which Optum excels. We also retain both the original electronic source data, the way in which it was received, and the normalized data to easily compare the two and be confident that our normalization procedures were accurate.

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Key findings:

- Based on an anonymous staff survey conducted at the end of the study, 83% of site staff indicated that they had an extremely high or high level of confidence in the accuracy and completeness of EHR data collected during the study.
- There were 2,152 study data records collected for 48 subjects as a result of the automated solution provided by Optum. Of these, 1,809 records represented the baseline and historical data collected, while 343 study records represented the data collected during follow-up encounters with the subjects. To quantify this further, each record equates to approximately 12 fields, which means that 25,800 data fields were populated by technology rather than requiring manual data entry.

Clinical Trial Manager and RN Peggy Preusse with Reliant Medical Group was directly involved with patients during the study. "Data collection and the query process was very easy and streamlined. In a normal study, those tasks take a lot of time and effort. If I were to estimate time saved, I would say it's 80% reduction in what we would usually do. Very simple. Very quick. Very efficient. Very timely."

Study findings

As for the observational study objective, 67% (or 33) of the 48 patients studied had a follow-up HbA1c lab result during the study. There were 21 subjects who showed improvement in their HbA1c (reduced value), 20 had a worsening HbA1c (increased value) and two had no change.

Approximately 25% (or 12) of the subjects received a modification in their anti-diabetic medication. These changes included either a change in dose or the addition of other medications. Greater improvements in HbA1c were seen in these patients. Unfortunately, many patients did not have a repeat in their HbA1c following the medication change before the end of the study.

As for the patient-reported outcome survey, the SF-12v2® (a validated subset of the SF-36) was administered at baseline and at the end of the study. Approximately 28 patients completed both surveys. Comparing these two results, both general health (+1.9) and mental health (+1.6) increased. Social functioning (-2.5) and limitations due to physical health (-1.7) declined (possibly associated with the ongoing COVID-19 pandemic). There was no significant change in physical component summary or mental component summary.

What all this means

Through this study, you can begin to see the evolution from traditional, manual, time-consuming clinical trials processes to a more modern, electronic and less burdensome future. All clinical trial agreement signatures and regulatory files were handled electronically. All study procedures were conducted remotely, such as eligibility confirmation, consent (eConsent) and patient-reported outcomes (ePRO). There was no manual data entry required and there was a significant reduction in the need for source data verification.

"What's really nice about this approach is that [Optum] provided all the software and tools to allow us to have a smaller and more efficient team, taking away much of the study burden. From my perspective, it was a piece of cake," said Dr. Garber. "This approach makes it easier for smaller practices to do research. Right now, most research is done by large provider organizations in big cities. But the majority of patients are cared for in smaller community practices, so this allows us all to get access to cutting-edge research convenient to where the patients live."

The study was able to demonstrate significant time savings in patient identification, more efficient data collection and management, and consistent data quality and integrity with less effort. All this should result in two very favorable outcomes for the future:

- An increasing likelihood of health care providers participating in clinical trials
- Better integration of clinical research into clinical care

Dr. Abbott summed it up this way: "With this study, we were able to integrate the research directly into the regular workflow of the clinic and eliminate many steps in the documentation process. It was great that our clinicians could just manage patients the way they usually do, not having to worry about other things."

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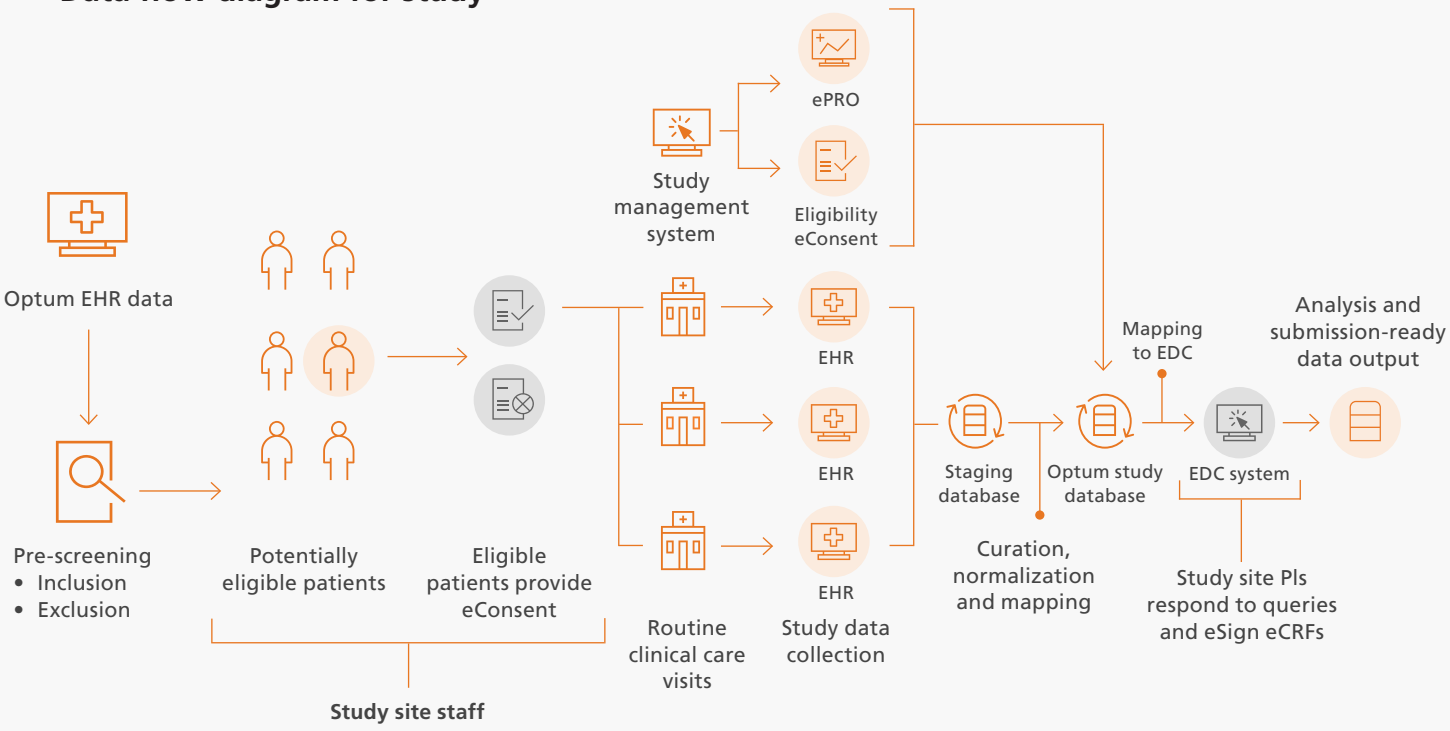
Data flow diagram for study



This study was made possible by the Optum® Digital Research Network (DRN). Its mission is to innovate clinical research by uniquely combining our data, technology, network and expertise to accelerate and reduce the cost of developing new therapies and improve the patient and provider experience.

If you would like to learn more about the Optum DRN, please visit **optum.com/life-sciences**

Sources:

1. Frost & Sullivan. Global Pharma Clinical Trial Patient Recruitment & Monitoring IT Solutions. Forecast to 2020. May 2018.
2. Penberthy LT, Dahman BA, Petkov VI, DeShazo JP. Effort Requires in Eligibility Screening for Clinical Trials. J Oncol Pract, 2012 Nov; 8(6): 365-370

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