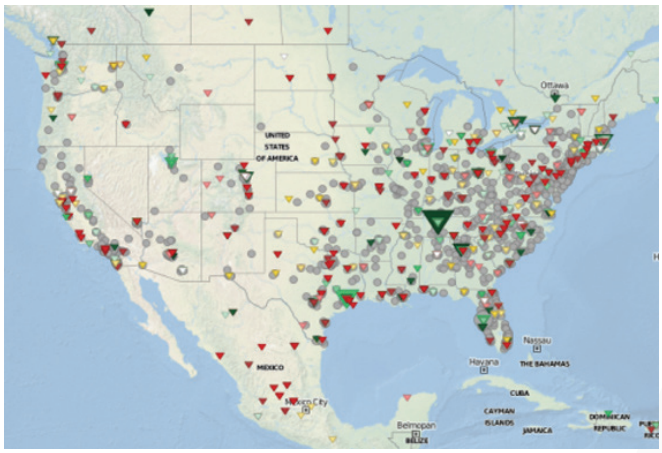
RESCUING PATIENT ENROLLMENT FOR A STUDY OF A RARE MUTATION

Case Study

Addressing Challenges to Support a Rare Disease Study



Applying Data-Driven Results

- LabCorp de-identified clinical laboratory data helped the planning teams locate difficult to find patients with a rare mutation.
- Increased recruitment activities in the U.S. using the LabCorp sales force to find new sites near AML patients.

A midsized pharmaceutical company was developing a treatment targeting newly diagnosed acute myeloid leukemia (AML) patients and selected Covance to support their global Phase III trial.

Finding participants is inherently difficult with AML because most newly diagnosed patients quickly start standard treatments. In addition, many physicians are not experienced as clinical investigators for this rare disease, adding to the difficulty of rapidly identifying and enrolling potential trial volunteers.

Applying Real-World Evidence to Select Sites

To overcome the challenge of finding investigators and patients, Covance relied on the LabCorp de-identified clinical laboratory data, which contains health information on 150 million de-identified patients tested on more than 5,000 clinical assays. Filtering by tests specific to AML within this rich dataset, Covance pinpointed the location of AML patient clusters and determined the optimal study sites based on location and specialty. To ensure selection of the most ideal sites, Covance reviewed data from their historical investigator performance statistics, which includes over 50% of the industry's global trial data to find AML-treating physicians with proven track records.

>5,000
ASSAYS

>50%
OF THE INDUSTRY'S GLOBAL TRIAL DATA

LABCORP PATIENT DATABASE INCLUDES MORE THAN
150 MILLION
PATIENTS

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Leveraging the Enterprise's Unique Infrastructure

While Covance was developing the sponsor's site identification and feasibility plans, the sponsor's competitor published interim results for a drug targeting the same indication. Suddenly, many of the sponsor's preferred trial sites were no longer viable options as they had extended their commitment to the competitor and could not support the sponsor's trial.

Responding to this critical development, Covance quickly revisited the LabCorp de-identified clinical laboratory data and identified physicians who treated AML patients to supplement recruitment activities in the US. Next, Covance worked with LabCorp representatives to reach out to these physicians and gauge their interest as a primary investigator, sub-investigators to pre-identified investigators at their institution or as a referral physician.

Success in Keeping a Trial on Track

Finding AML patients for a clinical trial is difficult and this particular situation with the rival treatment only intensified the pressure. However, Covance's flexible approach to address the situation by leveraging LabCorp de-identified clinical laboratory data represented an innovative solution to engage potential investigators and patients. The planning team was able to identify new channels to contact and revised its targeted site list as a result of the efforts. Now, with 274 sites across 28 countries, patient enrollment is on target with its forecast and the sponsor has a better chance of success in this competitive landscape.

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