IMPROVING RECRUITMENT THROUGH THE APPLICATION OF PROPRIETARY LABCORP DATA

Inclusion/Exclusion Criteria: A Case Study

A mid-size client wanted to run a cardiovascular (CV) outcomes Phase III study and sought advice from Covance regarding the protocol's inclusion/exclusion criteria.

Understanding the Challenge

The client had very precise inclusion criteria to test their lipid-modifying therapy. They sought patients with Type II diabetes with triglyceride levels of 200-500 mg/dL and high density lipoprotein cholesterol (HDL-C) levels of ≤ 40 mg/dL. Along with these limiting criteria, the client faced:

- An inherently competitive CV recruitment space for a large-scale study
- Limited patient availability for this indication despite a high number of potential patients
- A high screen failure rate for their study based on data from initial literature reviews

Mining the LabCorp Database to Optimize the Protocol

Together with the client, Covance evaluated the lipid inclusion criteria and modeled potential scenarios using de-identified patient information from the LabCorp database, which contains more than 75 million de-identified patient test results.

Looking at the patients in the LabCorp database with Type 2 diabetes and filtering by the specific inclusion criteria, Covance found that only 16% of the potential patient population would qualify for the client's study.

While the client remained adamant that their protocol remain unchanged, Covance ran a second simulation to determine if minor modifications that would not affect the scientific validity or the integrity of the study could make a difference to the size of the potential patient pool.

By increasing the HDL-C entry criterion in female patients from ≤ 40 mg/dL to ≤ 45 mg/dL and modifying the overall triglyceride entry range from 200-500 mg/dL to 180-600 mg/dL, the team found that the potential patient population increased by over 150% from 1.23 million to 3.1 million.

Value to the Client

As a result Covance's proactive leadership, combined with access to proprietary real-world data from LabCorp, the client gained new insight into its potential patient base and better understood the impact of their protocol's inclusion/exclusion criteria on upcoming enrollment efforts.

The client concluded that Covance's suggested modest changes in lipid values would not impact the study's scientific objectives, and made the recommended modifications to their study protocol. As a result, the client drastically increased their potential patient population–setting their study up for stronger success in a crowded indication in which time is a crucial factor.

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