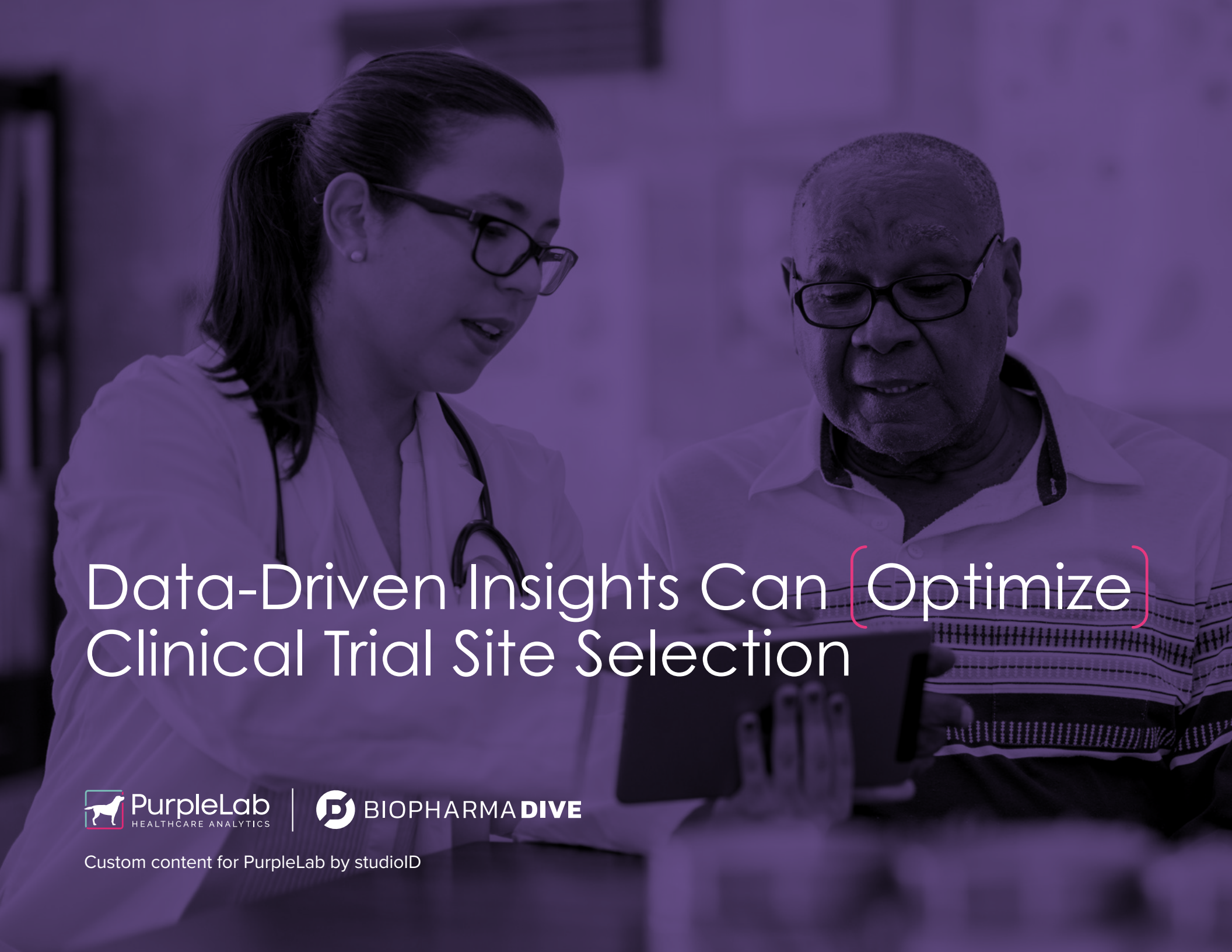

Data-Driven Insights Can Optimize Clinical Trial Site Selection

PurpleLab HEALTHCARE ANALYTICS | BIOPHARMA DIVE

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It takes an average of 12 years to bring a new drug to market.[1] Clinical trials, an essential part of the drug development lifecycle, could be holding up the process.

Ninety percent of clinical trials fail to hit their timelines (and delays can extend projected timelines up to 50 percent.[2,3] Poor site selection is often to blame.

"Site selection is one of the critical elements for conducting a clinical trial," says Jason Gagner, vice president of product management for life sciences at PurpleLab. "The risks [of poor site selection] are pretty significant."

Site selection is crucial for the successful completion of clinical trials. Although the right sites can optimize participation and reduce disruption of trial timelines, there are no detailed guidelines for the systematic selection of clinical trial sites. Using data-driven insights to optimize site selection and help select referring clinicians, recruit and retain high value patients can power successful clinical trials and accelerate innovation.

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The Trouble with Site Selection

Poor site selection is associated with protocol violations, poor quality data, missed timeliness and increased costs; site selection can also affect patient recruitment.[3] In fact, **11 percent** of clinical trials fail to enroll a single participant and **37 percent** of trials that enroll participants either under-enroll or struggle to retain them for the duration of the trial.[4]

Issues with patient recruitment can result in underpowered studies, delays in drug approval and, in some cases, trial terminations.[5] It's one of the reasons that pharma companies and CROs cited recruitment related factors as the most important factors in choosing clinical trial sites.[6]

Even sites that are enrolling patients can face consequences of poor site selection. Gagner notes that site-related issues like inadequate staffing and lack of appropriate infrastructure could result in poor quality results and trial delays. **Delayed timelines can cost pharma companies up to $8 million per day**.[7]

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"The obvious risk [of selecting the wrong site] is that it doesn't perform," he adds. "You can spend months trying to enroll a site and significant financial resources to get a clinical site up and running and, if it's the wrong site, time and financial resources are lost. The right site can help alleviate those pitfalls that could delay the development of a treatment."

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Site Struggles

A recent survey asked sites, sponsors and clinical research organizations (CROs) about their current site challenges.[8]

These were their top 10 responses:

1. Site Staffing and Retention — **63%**
2. Patient Recruitment and Enrollment — **48%**
3. Study Start-up — **36%**
4. Complexity of Clinical Trials — **36%**
5. Long Study Initiation Timelines — **23%**
6. Physician Interest and Engagement — **19%**
7. Technology — **18%**
8. Trial Financial Management — **18%**
9. Patient Access Challenges — **16%**
10. Remote Monitoring — **9%**

Current Approaches to Site Selection

Traditional approaches to site selection have included assessing prior trial participation and investigator, site and enrollment data sources to estimate performance.[5] Epidemiologic and geographical analyses was also used to identify potential sites with research experience and access to a sufficient target patient population.[5]

Feasibility assessments that examine whether sites are capable of conducting clinical trials or suitable for specific trials have been called "costly, inefficient, unnecessarily burdensome and resource intensive."[9] These challenges have created an urgent need to improve the assessment of clinical trial feasibility.[10]

The COVID-19 pandemic altered the site selection process and forced biopharma companies that often worked with the same investigators and institutions and relied on internal databases and personal referrals for site selection to change their approaches.[11]

"Prior to COVID, site selection was challenging because of the time needed to fully qualify a site with an informatics assessment plan, evaluating the patient population and the [principal investigator]," Gagner says. "During COVID, many healthcare systems reduced their clinical trial participation ad they lost that support infrastructure; post pandemic, many of those healthcare systems have not fully staffed up or returned to the same type of clinical trial support that they had prior to COVID."

To evaluate the capabilities of an institution, Gagner suggests looking at current data on their patient populations, principal investigators, publications and clinical trial participation to avoid selecting sites based on outdated information, adding, "Having up-to-date data is critical to help overcome some of those challenges with site selection."

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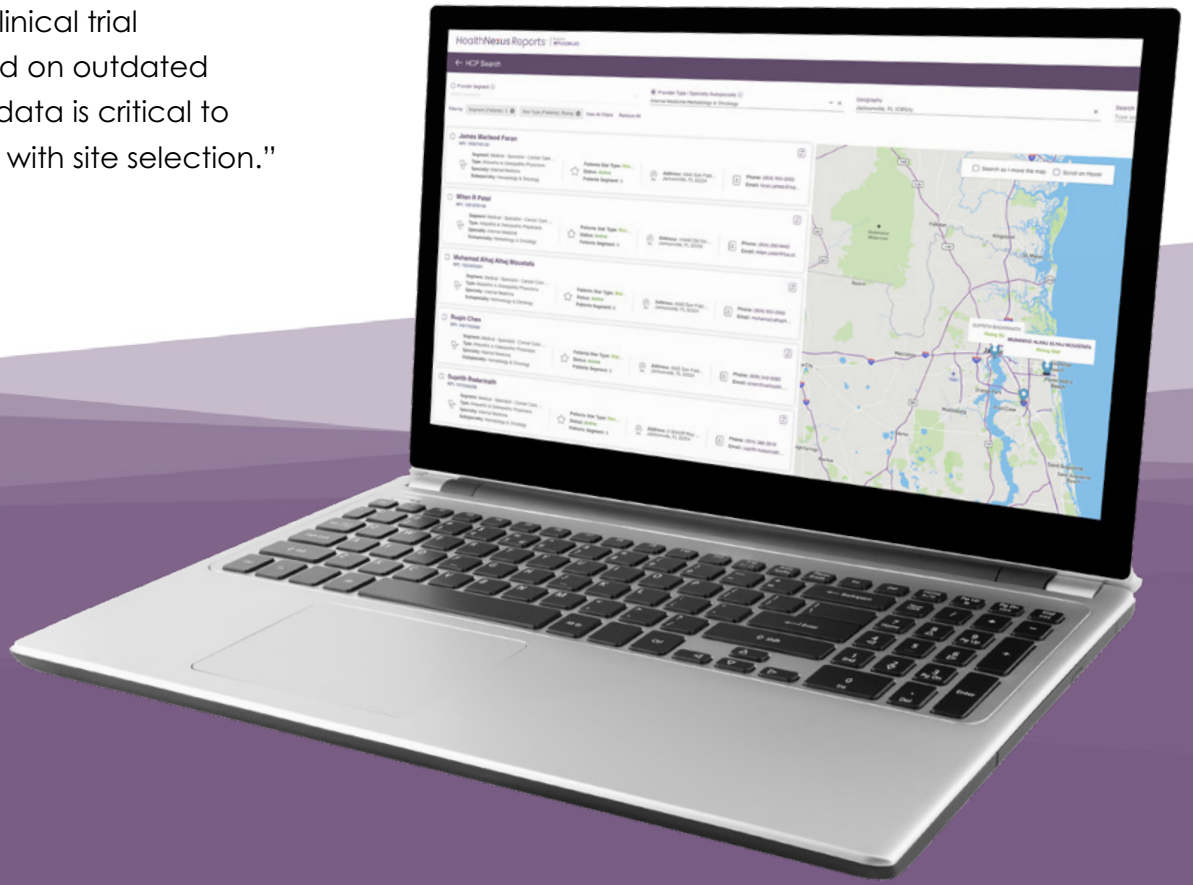

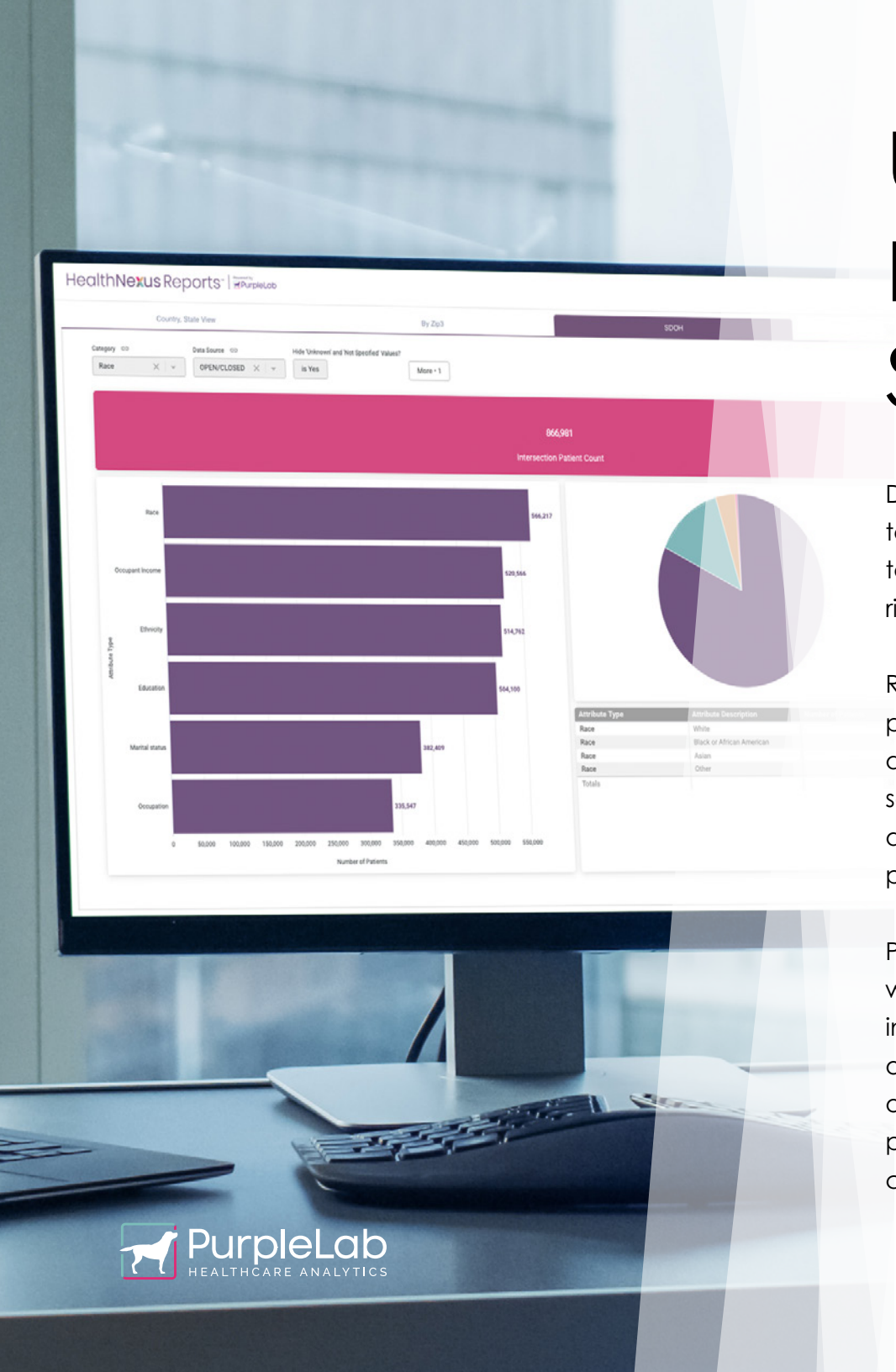

Unlocking Data to Improve Site Selection

Data is critical for site selection. Pharma companies that "fail to…analyze data to determine the probability of achieving their target outcome when making their site selection decisions are at risk of falling behind their industry peers." [11]

Rather than existing in a silo, biopharma companies are partnering with providers who have data capabilities to take advantage of large data sets to enhance clinical trial site selection and research has shown that a machine learning approach that incorporates site level recruitment and real world patient data outperforms traditional methods of site selection.[5,11]

PurpleLab uses real world evidence (RWE) generated from real world data (RWD) to generate deep insights into site capabilities, investigators, staff, patients and the role of evidence in patient outcomes. Incorporating data about the social determinants of health (SDOH) is also valuable to ensure that clinical trial participants represent the population who are diagnosed with a condition and might benefit from the treatments being studied.

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"Understanding the potential of a site for a particular condition is essential in hitting study milestones and removing barriers to patient recruitment," says Amy Crowe, vice president of go-to-market enablement for PurpleLab. "RWE can help companies understand which investigators see the most patients, frequency of care, and other factors that impact studies. To meet FDA requirements for diversity, being able to see easily see SDOH factors by site and investigator helps prioritize sites."

Biotech companies and smaller pharmaceutical companies often lack access to performance data. Without it, Gagner explains, it's possible to select the right clinical trial sites but the process requires more time and resources to conduct literature reviews, identify sites and principal investigators for trials and doing outreach to convince them to sign on. Gagner calls it possible, but adds, "It would slow everything down, and not by a magnitude of weeks or months but by years."

PurpleLab offers tools to help biopharma companies with site selection for clinical trials. Investigator Profiles provide detailed data about investigators, including their participation in research, publications and conferences, funding sources and thought leadership experience to help biopharma companies identify potential principal investigators for their clinical trials. Site Profiles provide similar information, offering a deep dive into the data related to possible clinical trial sites.

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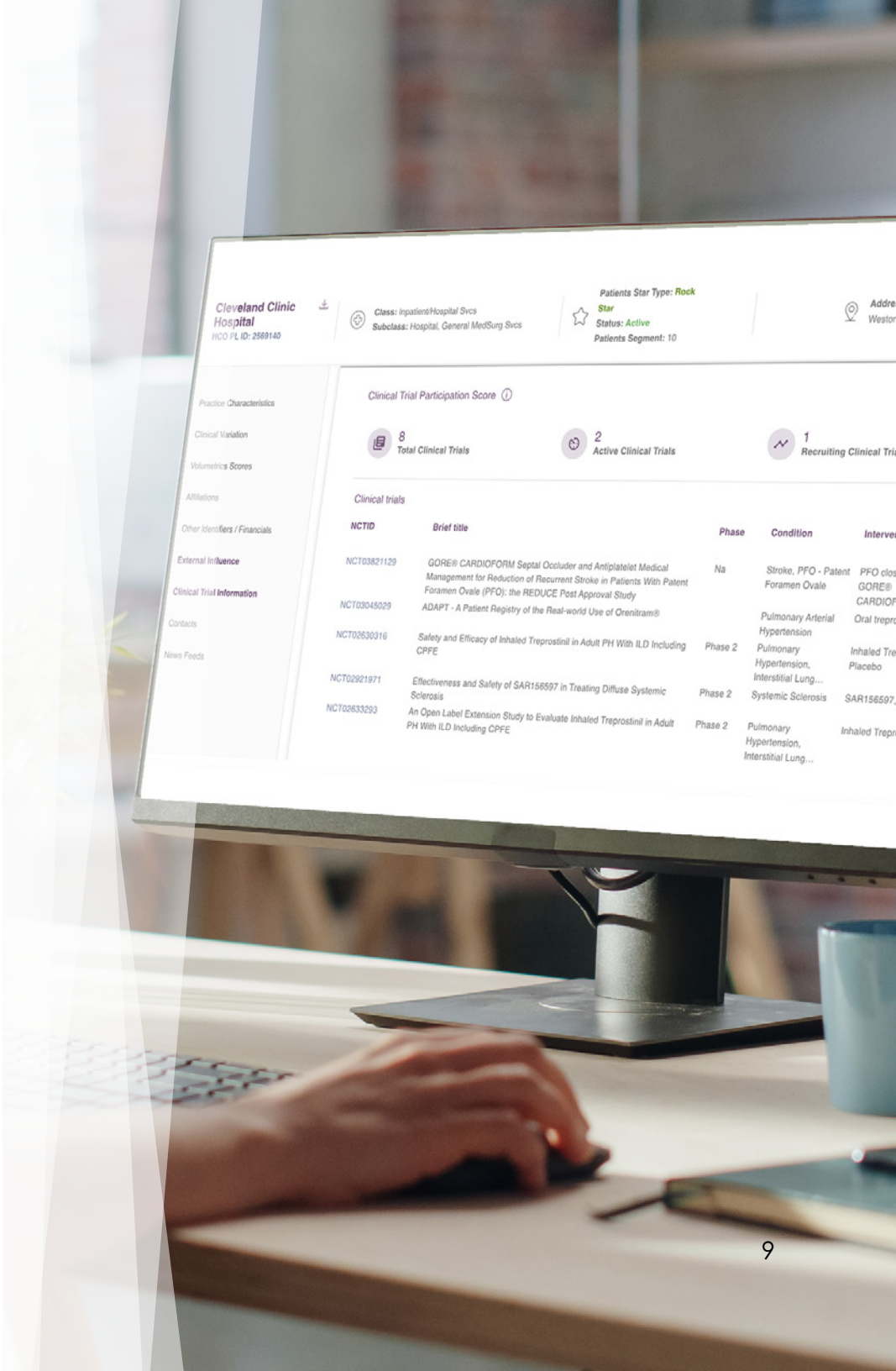
AMY CROWE, VICE PRESIDENT OF GO-TO-MARKET ENABLEMENT FOR PURPLELAB

"We have done the hard work of combining disparate data sources of clinical trial information to give you an up to date and easy to use picture of each investigator and site," Crowe adds. "You can easily see a table of each investigator and site and prior study experience including condition, companies worked with, phase, and timeline."

Comprehensive Layout for Exploration, Analysis, & Research (CLEAR) Claims transforms raw claims data from multiple sources into streamlined in-platform insights and enhances RWD capabilities optimize the analysis and interpretation of healthcare data.

Gagner refers to CLEAR Claims data as "removing the noise from healthcare data." It validates diagnoses data, providing information on patients and the sites were patients receive care and clarify claims where a potential diagnosis is used for the justification of a lab being ordered.

"We're taking 20 years of historical experience of curating and harmonizing data and building out the methodologies around it," Gagner says. "It's not just about having a high volume of data, but elevating the level of quality of that data—that's what makes PurpleLab stand out."



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Data for Diversity

Clinical trial enrollment should reflect the population that is most likely to use an approved drug but challenges to achieving diversity remain. In 2020, the U.S. Food and Drug Administration released guidance to help sponsors increase enrollment of underrepresented populations in clinical trials. The recommendations include guidance on using site selection to increase clinical trial diversity.[12]

The FDA recommendations suggest including sites in geographic locations with higher populations of racial and ethnic minorities; the guidance also suggests considering the diversity of healthcare providers and study coordinators to assist with clinical trial recruitment because some participants may prefer healthcare providers who share their ethnic or cultural backgrounds.

"We have partnered with top Life Science and CROs to help them meet FDA recommendation on diversity," Crowe says. "PurpleLab has SDOH data at a patient, investigator and site level that allows greater precision in finding the best sites to can help meet these requirements."

Reach out to PurpleLab today to find out how we can assist in clinical trial development, protocol design, investigator selection, evaluating patient populations and more.

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PurpleLab is your preferred partner for real-world data. We provide valuable insights into the health of the US population. Going beyond raw claims data, we offer longitudinal patient data and on-demand information about payers and providers. To protect patient privacy, we de-identify our data to ensure HIPAA compliance. We collect healthcare observations from clearinghouses, payers, and other data partners. Our data warehouse has information on approximately 330 million patients, integrated across both open and closed claims data sets. Our platform, HealthNexus, manages all the complex intersections of disparate healthcare vocabularies and provides precise and usable insights in a matter of minutes.

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