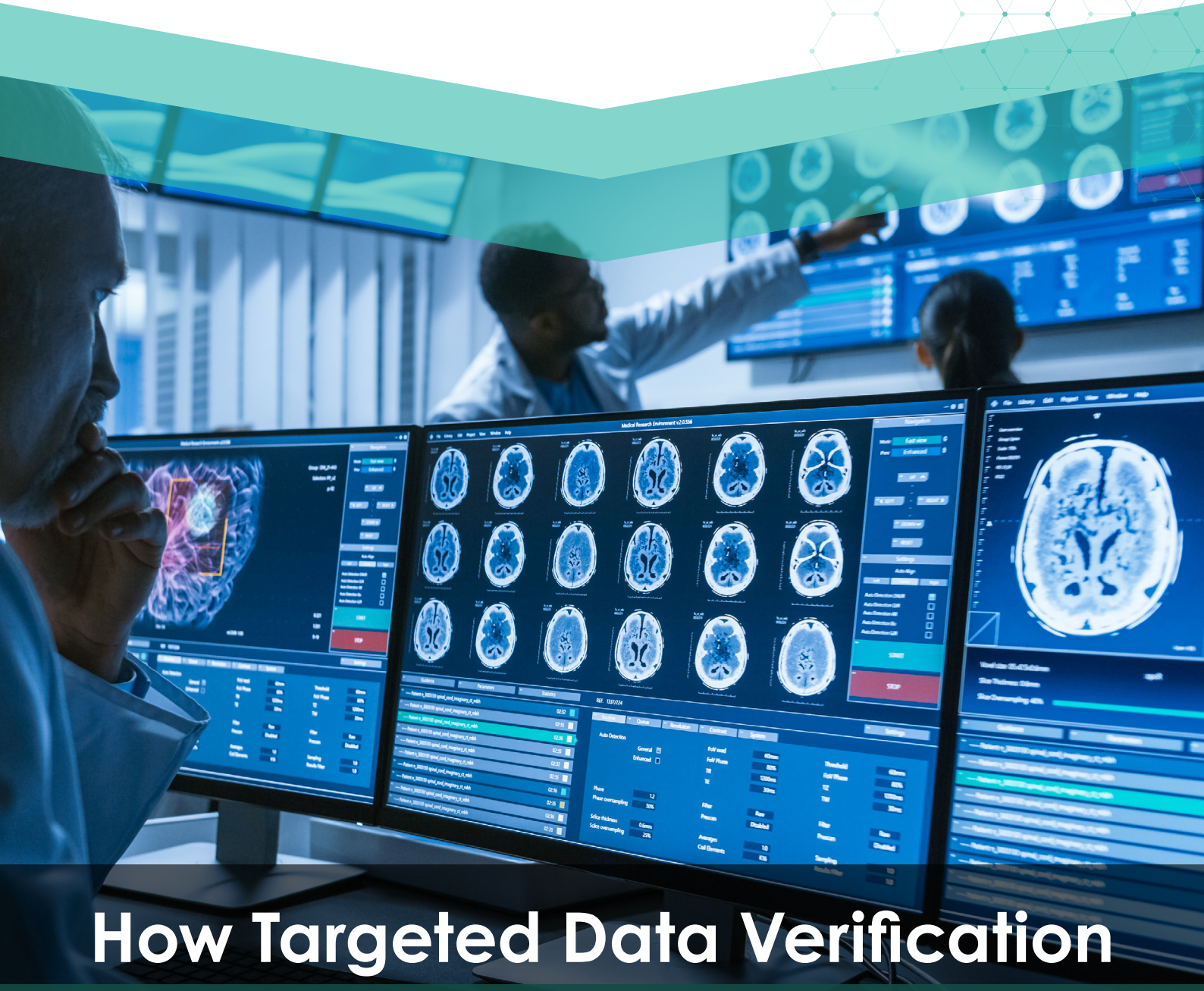
REMARQUE SYSTEMS SM



How Targeted Data Verification Reduces Risk in DCTs

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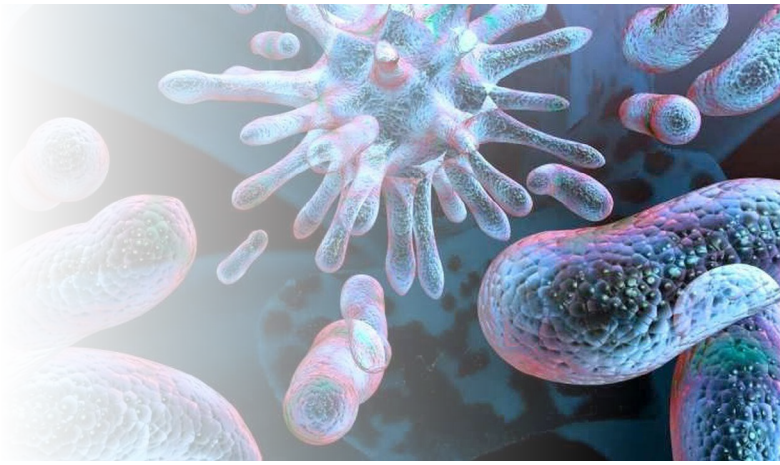
Imagine your decentralized clinical trial (DCT) is over budget, under-enrolled—and you need to change your data monitoring platform. Worse, the trial is producing a continuous stream of disaggregated data. A clinical research organization (CRO) recently approached Remarque Systems for help with precisely this problem.

Our goal was to enable the CRO to reduce the time-and by extension the cost—spent on data verification, allowing them to swiftly uncover anomalies so that the study team could take quick action to reduce risk and improve patient safety. We responded with a combination of consulting and technology.

By centralizing all data on the Remarque platform, then harnessing our expertise to identify the most pertinent data, we were able to support the logistical challenges of changing data management platforms and examine the data in a more cost-effective and actionable way.

CUSTOMER INTRODUCTION

This European-based pharmaceutical company develops drugs influencing the human infant microbiome to prevent or treat rare diseases affecting premature infants. The company is primarily concerned with fulfilling unmet needs for conditions with no preventative or therapeutic options available.



THE CHALLENGE

The CRO engaged in 100% source data verification (SDV)—and had fallen far behind. They realized that they needed to change their data monitoring platform. In addition, with a raft of unexamined and unverified data, they needed guidance prioritizing which data to monitor first. They were anxious to identify those patients at highest risk for data integrity and data safety issues—but were at a loss as to how, precisely, to pinpoint them.

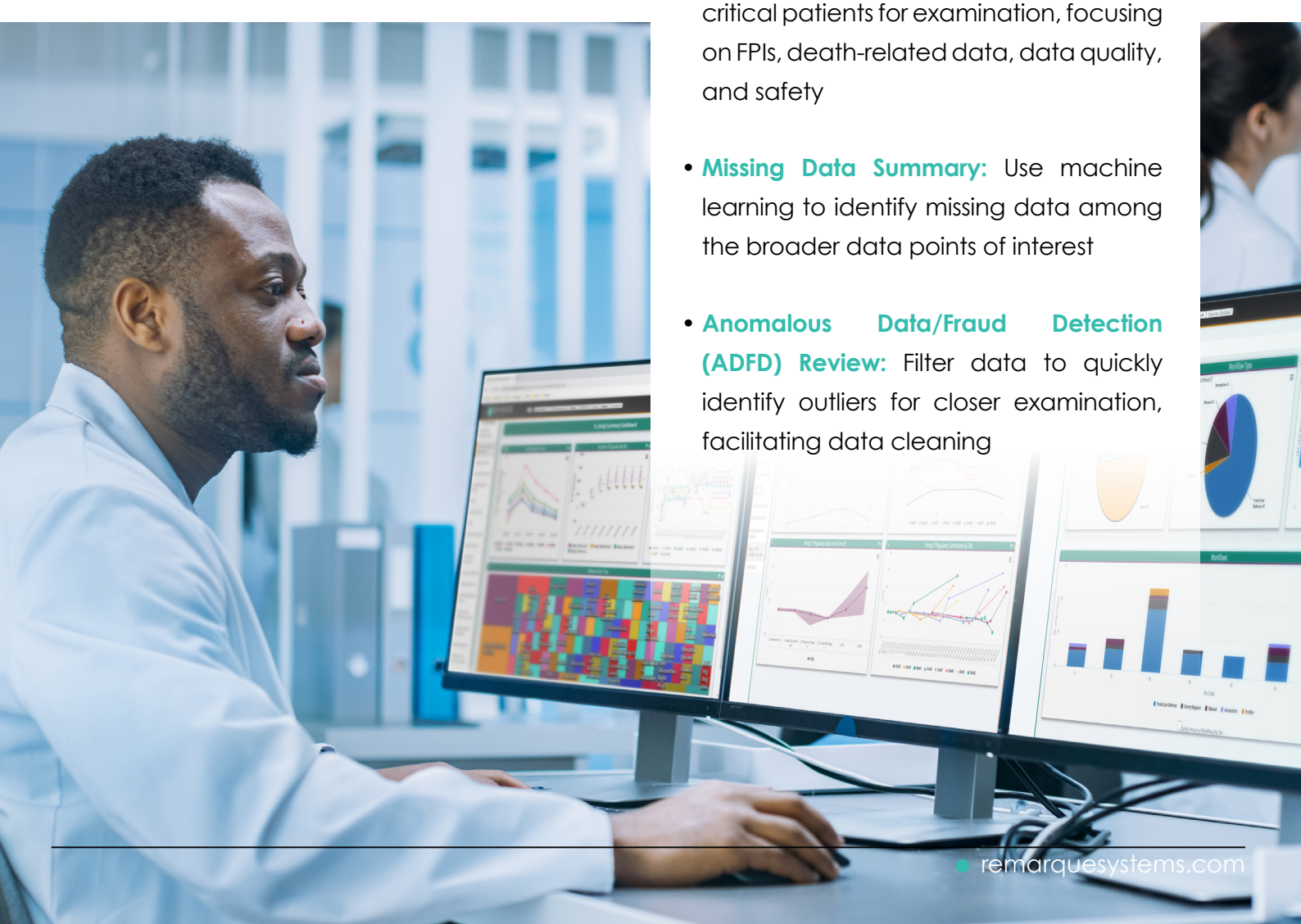
THE APPROACH

Because the Remarque Systems platform is source-agnostic, we could seamlessly transfer all the study data onto our platform, from which the CRO could easily monitor the data. We even programmed some examples, so the sponsor could understand the insights they would be able to glean from Remarque's specific charts, graphs, and lists.

Then, armed with the study team's specifications—including a desire to examine the first patient enrolled (FPI) data at every site—we created a risk-based monitoring (RBM) strategy.

We built a flow document so the CRO could deploy different roles to examine data in various formats to seek specific deviations. Then we developed a three-pronged analytics plan to identify the patients at higher risk and the data points in need of review:

- **Patient scoring:** Target data of the most critical patients for examination, focusing on FPIs, death-related data, data quality, and safety
- **Missing Data Summary:** Use machine learning to identify missing data among the broader data points of interest
- **Anomalous Data/Fraud Detection (ADFD) Review:** Filter data to quickly identify outliers for closer examination, facilitating data cleaning



THE RESULTS

A chief challenge of DCTs is the plethora of disaggregated data—which raises analogous challenges for SDV. By centralizing the data on the Remarque platform then applying an RBM strategy, the CRO streamlined SDV while swiftly identifying anomalies.

The CRO was able to roll out the analytics plan to their study team—and ultimately, to the sponsor.

Ultimately, they could save time, reduce costs, and minimize risk both for the sponsor and for the patients.

Triaging SDV

Targeting the most relevant and risk-related data points can save time and money and reduce risk.

Data of interest

Data that must be monitored onsite

Data at risk

- Sites with the highest ADFD
- Sites with the most missing patient data
- Sites with the highest overall risk

Investigate issues, support list with supporting data to onsite monitor

Onsite monitor conducts SDV, queries and updates data

Documentation complete

- Examine data in another at-risk subset