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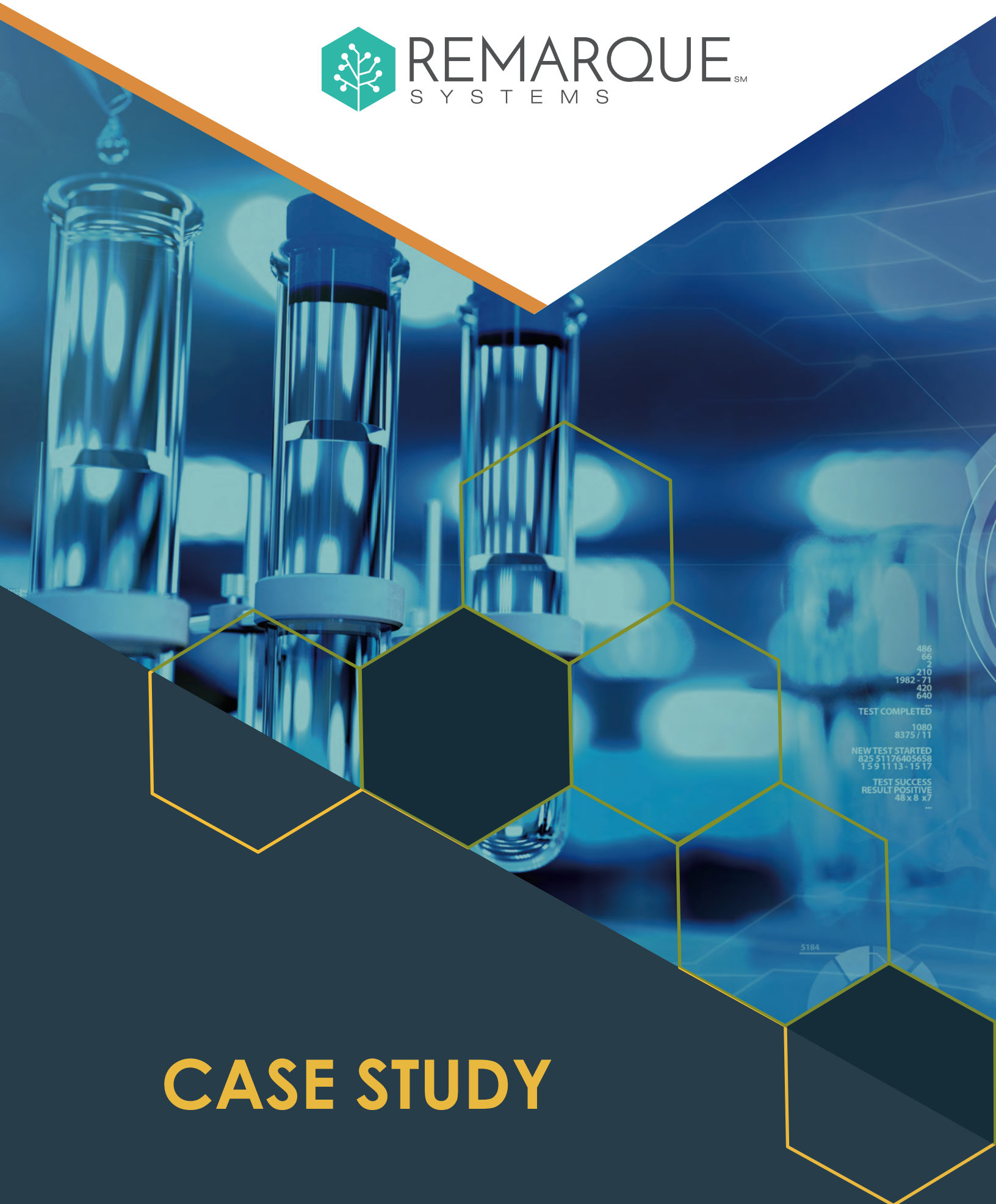
SYSTEMS



CASE STUDY

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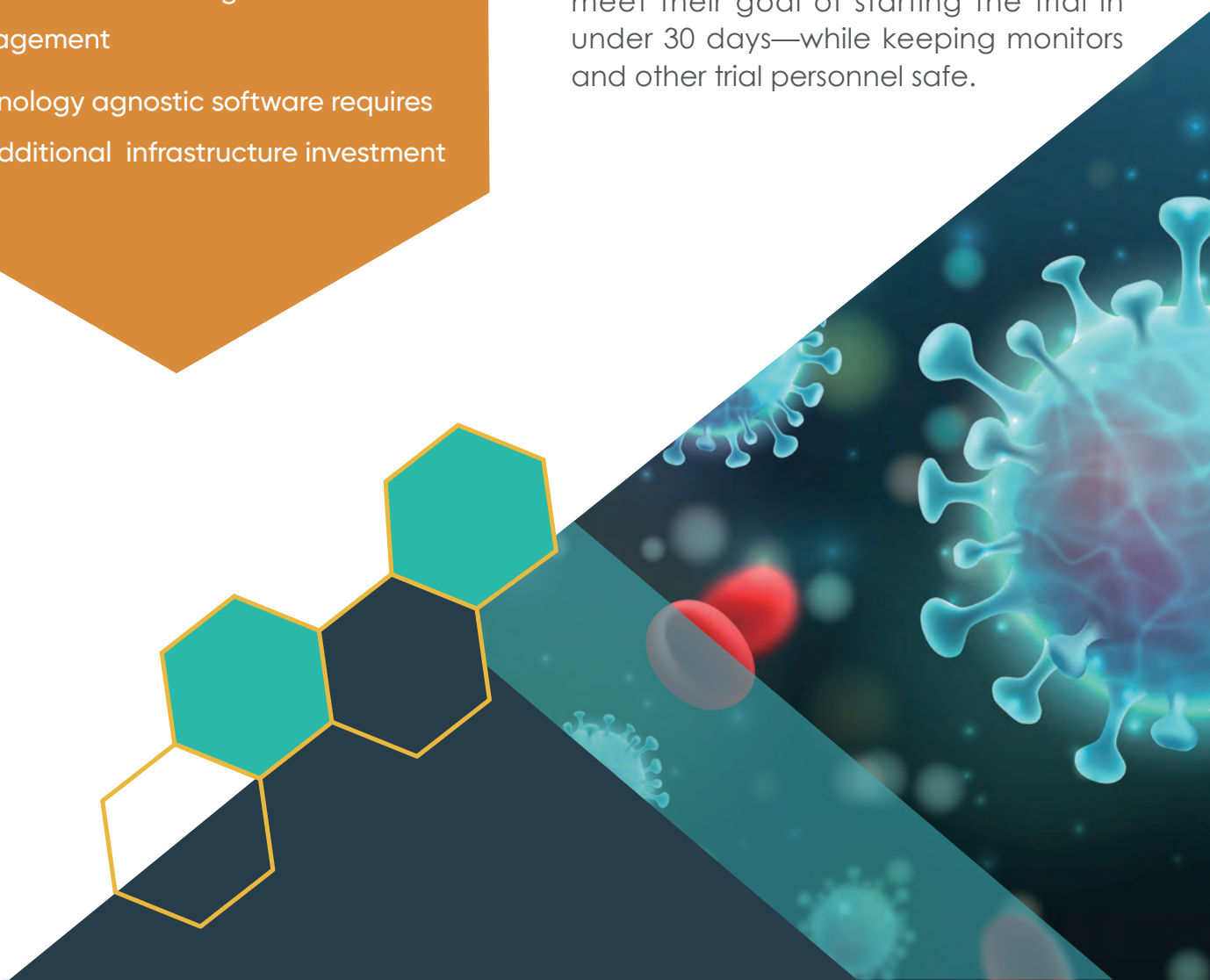
REMARQUE SYSTEMS

Rapid Start-up and remote monitoring enable trial in COVID-19 population

The Highlights

- Trial start-up in < 30 days
- Fully remote monitoring and management
- Technology agnostic software requires no additional infrastructure investment

A leading pharmaceutical company was poised to begin phase 3 trials for a potential therapy for COVID-19, testing in patients with symptomatic COVID-19 infection. Every moment mattered. Yet traditional methods—involving consistent in-person interaction—were clearly not viable. By harnessing the power of the Remarque Systems platform, the pharma company has been able to meet their goal of starting the trial in under 30 days—while keeping monitors and other trial personnel safe.



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THE BACKGROUND

This prominent global specialty pharmaceutical company markets therapeutic solutions for patients with life-threatening conditions and chronic illnesses. With a strong track record of success in respiratory illnesses, they are wellpositioned to apply their expertise to help treat patients suffering from COVID-19. That realization has heightened the pressure to accelerate the pace of their clinical trials in hopes of helping save tens of thousands of lives.

THE CHALLENGE

The pharmaceutical company was racing to test a therapy with the potential to shift the trajectory of a global pandemic—and at first there were serious potential roadblocks. Trial start-ups can be notoriously slow—and they wanted to start in less than a month. Moreover, clinical trial monitoring traditionally requires much in-person contact, which would need to be reimagined. Technology could be used to address safety concerns, using tools for electronic data capture and even monitoring and analysis. Yet these often require significant infrastructure investment or else long lead times to build specialized programming that enables one system to "talk to" another system. There was no time to build a custom solution.

For such rapid start-up and execution to succeed the company would need:

- Sites with active, onsite clinical research staff, active IRB with rapid turnaround, and a significant caseload of COVID-19 patients
- An accelerated database build
- Electronic data capture
- The ability to conduct remote site-qualification visits, training, data processing, and monitoring

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THE APPROACH

The company was delighted to find the Remarque Systems platform. Technology agnostic, Remarque is able to aggregate data from any electronic output—including EDC, IRT, and CTMS systems, as well as wearables, electronic medical records (EMRs), and other sources. It can be deployed immediately and requires no additional software or hardware to implement its features. That meant the company could work with sites' existing EMRs and choose best-in-class options for the additional technology needed.

In addition, the Remarque platform is purpose-built to run clinical trials, centralizing monitoring activities and patient data on easily visualized dashboards; allowing direct management, tracking and auditing at the site level; and applying advanced machine-learning algorithms to predict, detect, analyze, and manage risk.

Working with Remarque, the pharmaceutical company was able to:

- Accelerate database build through a modular approach, beginning with data collection, then adding customized programming
- Easily program data collection systems with reference ranges for each lab to identify and flag out-of-range results swiftly
- Conduct virtual site qualification visits using camera-enabled technology as necessary
- Hold remote site initiation visits (SIV) immediately following the receipt of full approval and release of study drug and Metered Dose Inhaler (MDI) so that site activation occurred expeditiously
- Capture source data and documents in real-time from both sites and patients, ensuring streamlined data entry and rapid review and access, decreasing cost, and increasing data quality
- Employ a mobile application for electronic patient-reported outcomes, maximizing compliance and adherence
- Use Remote Monitoring to review safety and endpoint data, as well as all other business pertinent to integrity of data collected on study
- Perform remote Source Data Verification (SDV)

In short: They were able to launch the study in record time, while maintaining the safety of the trial team.

In choosing Remarque System's platform, a leading pharmaceutical company secured a trial-transforming technological advantage for their COVID-19 trial—one that accelerated start-up while securing the safety of the trial team.

www.remarquesystems.com