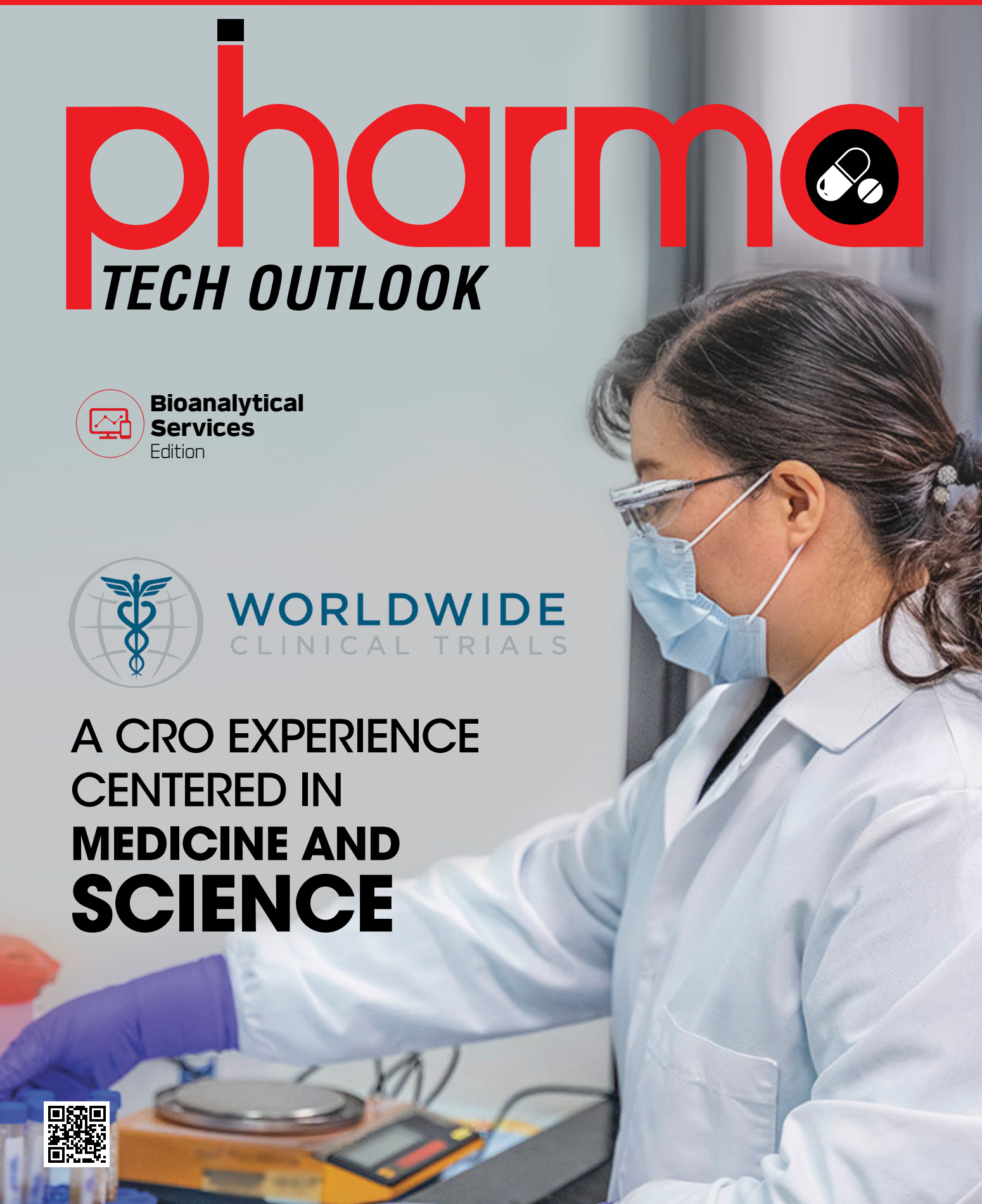
pharma TECH OUTLOOK

Bioanalytical Services Edition

WORLDWIDE CLINICAL TRIALS

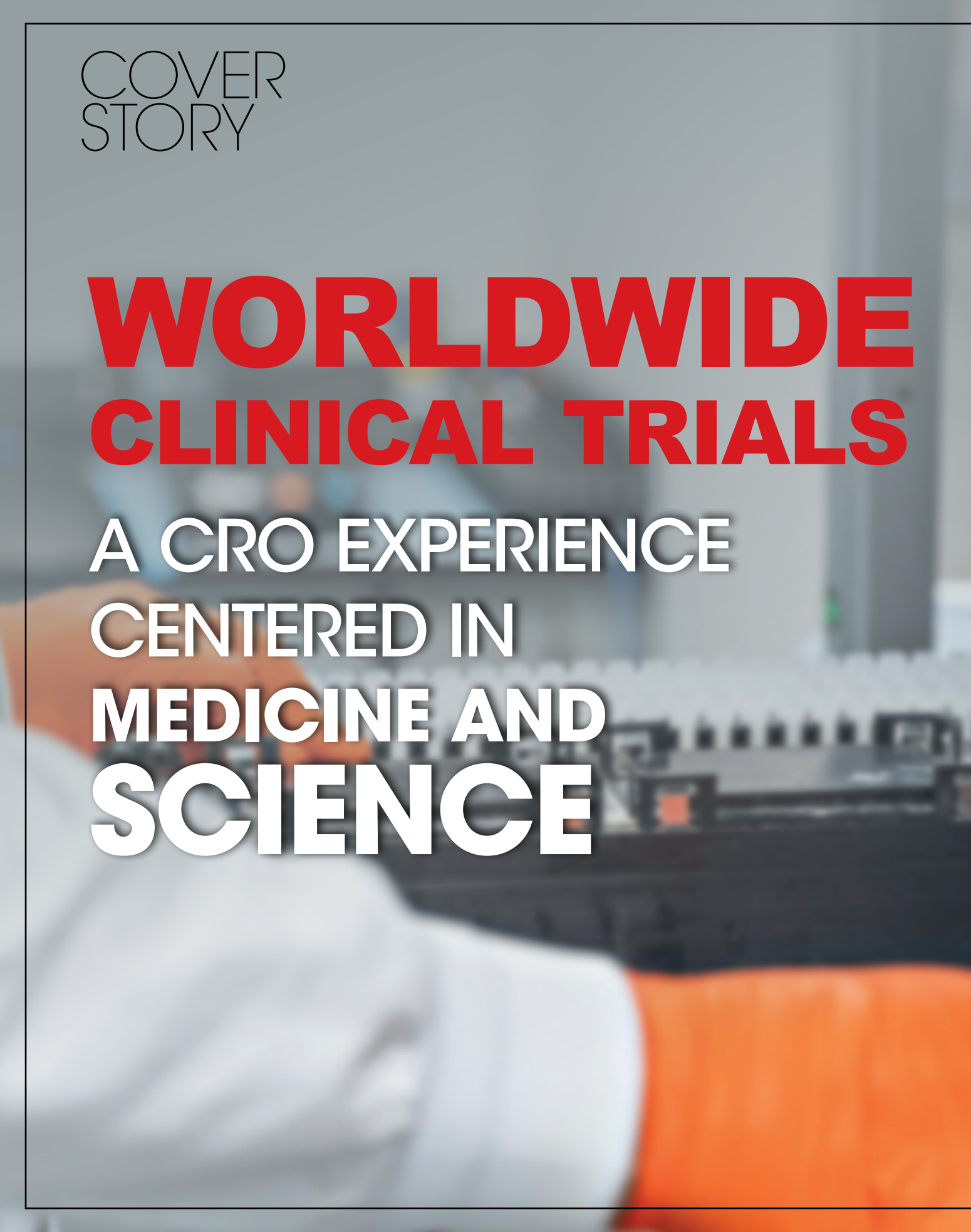
A CRO EXPERIENCE CENTERED IN **MEDICINE AND SCIENCE**



COVER STORY

WORLDWIDE CLINICAL TRIALS

A CRO EXPERIENCE CENTERED IN MEDICINE AND SCIENCE



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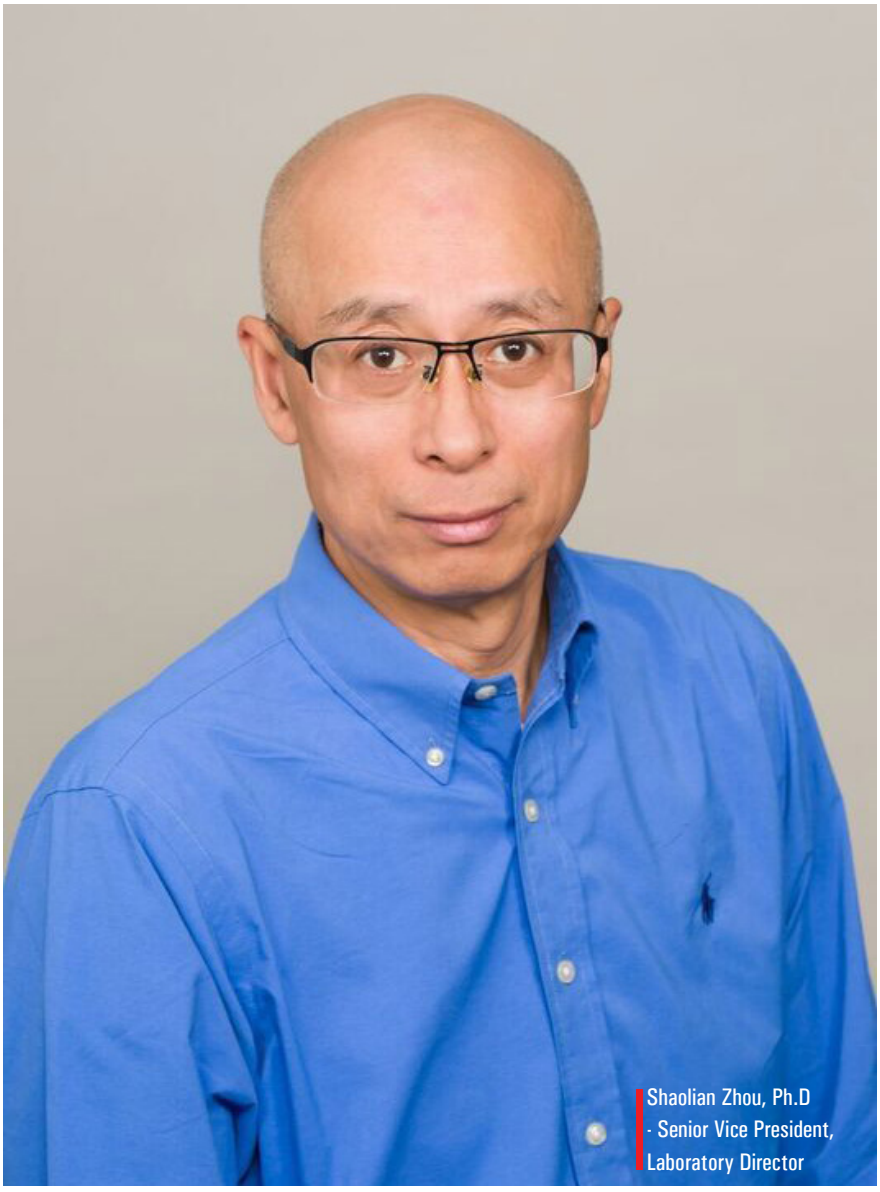
TOP 10 BIOANALYTICAL SERVICES COMPANIES - 2019

We have always been focused on delivering uncommon value via people, processes, and tools across the drug development process



Shaolian Zhou, Ph.D
- Senior Vice President, Laboratory Director

With each passing year, an increasing number of China-based biotechnology startups are looking to go global, particularly targeting the U.S., which still holds a dominant spot in the rapidly-growing biotech industry. The U.S. constitutes a $300 billionshare in the biotech market, driven by its world-leading academic institutions, research labs, and pre-eminent biotech companies. Critically, the U.S. is home to a robust capital market that a number of overseas biotechs are hoping to tap into.

However, to successfully penetrate the U.S. market is a mighty tall order. The challenges could vary from government-imposed restrictions on working visas and academic exchanges, limits on the ability of foreign companies to outsource biotech research, and the withholding of the U.S. regulatory approvals, which are regarded as the global benchmark.

Just take the example of one such Chinese biotech firm, which ran into severe issues—such as stability concerns for its molecules—while planning its first-ever Phase-1 clinical trial in the U.S. In the lookout for a seasoned CRO—to navigate through the challenges—the biotech firm visited

Worldwide Clinical Trials' bioanalytical lab in Austin, TX. While surveying the state-of-the-art facility, the sponsor was introduced to the CRO's quality and scientific expertise in bioanalytical sciences, and, more importantly, to the approaches taken by Worldwide to tackle specific bioanalytical challenges.

The tour ended on a familiar note as the biotech firm selected Worldwide as its partner for clinical trials. "We shared with them our vast knowledge and procedures for stabilizing similar drug molecules and our ability to expedite their timelines for both the bioanalytical and pharmacokinetic aspects of their study," says Shaolian Zhou, SVP of Worldwide's highly-advanced bioanalytical lab.

Today, the Chinese biotech firm is one of many clients that benefit from Worldwide's full-service drug development services, starting from earlyphase and bioanalytical sciences through late phase, to post-approval and real-world evidence studies. With infrastructure and talent spanning 60 countries, Worldwide has a proven track record of executing predictable, successful studies with operational excellence across therapeutic areas like the central nervous system, cardiovascular, metabolic, general medicine, oncology, and rare diseases.

We put our money where our mouth is. We also have an unwavering commitment to methodological rigor

Founded on Science, by Scientists

In scripting countless success stories for clients, Worldwide has effectively answered the million-dollar question: can a CRO truly serve as a partner of the sponsor?

Traditionally, CROs were hired by sponsors in exchange for certain capabilities that were otherwise not available within the sponsoring organizations. Through the years, however, the CRO-sponsor affiliation has evolved into a strategic partnership, and not merely a transactional one.

As a matter of fact, Worldwide deserves a plethora of credit for this industry-wide sea change. With origins dating back to 1986, Worldwide—established in 2007 by Neal R. Cutler, M.D., CEO; Angelico Carta, M.D., President; Michael Murphy, M.D., Ph.D., Chief Medical and Scientific Officer; and Henry J. Riordan, Ph.D., EVP, Medical and Scientific Affairs—stood out among its fellow CROs from the very onset.

Since it was "founded on science, by scientists," Worldwide could instantly engage with sponsors, view protocols, look at patient care, analyze data, and ensure quality, in a manner that is unprecedented for a CRO. "We have always been focused on delivering uncommon value via people, processes, and tools across the drug development process. Everything we do is infused with our focus on science and medicine," adds Zhou.

The founders' vision, to challenge the status quo of the traditional CRO, has been sustained to this day. Out to change the way in which biotechs and pharma companies experience CROs—in the best possible way—Worldwide's unified goal remains to delight its customers and deliver flawless services. It stands to reason why Worldwide is able to provide on-time, on-budget qualitative CRO services by strictly adhering to its partnership principles, to ensure successful alliances.

For study design, Worldwide focuses on principles such as team alignment, strong feasibility, protocol agreement, and early and frequent communication. With regard to financial management, the CRO hangs its hat on offering competitive pricing.

The sponsors that have collaborated with Worldwide would be the first to attest that the CRO is predictive, easy to work with, and thorough with compliance. When it comes to operational excellence, Worldwide has maintained a spotless high say/do ratio, clearly-defined deliverables, and frequent story updates. As such, the CRO ensures that governance is in place and that escalation processes are identified in a timely manner.

Meeting Sponsor Timelines with Efficiency

When it comes to clinical trials, time is of the essence. Although Worldwide does not take any shortcuts in delivering high-quality CRO services, it has developed a number of unique approaches to swiftly and successfully meet sponsor-determined timelines.

First, Team Worldwide—comprising 1,700 professionals across the world—ensure that its validated assays are highly rugged to avoid or minimize repeat analysis.

Secondly, Worldwide makes it a point that its team of analysts is well trained and pre-qualified before analyzing a sponsor's sample.

Furthermore, from a technological perspective, Worldwide utilizes automation and multiplexing, allowing

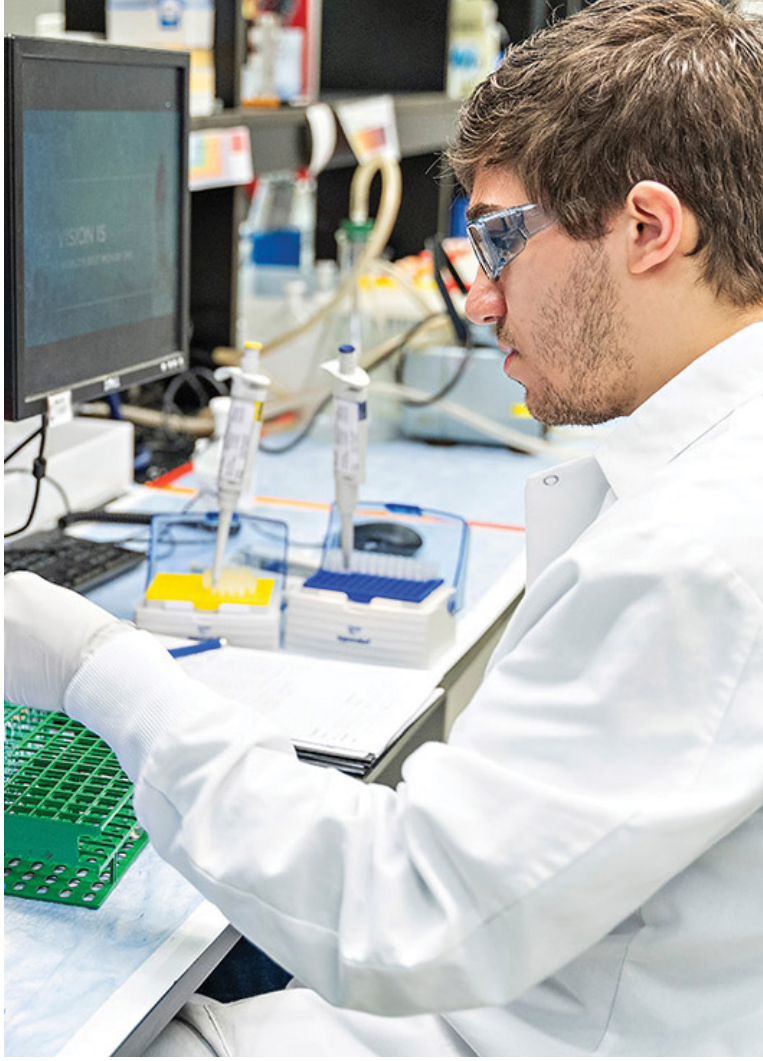
for maximized productivity. Lastly, it has an established, streamlined workflow to guarantee that every phase in the bioanalytical process is highly synergetic from method development, validation, and sample analysis to data review and reporting.

Besides banking on its tried-and-true methods, Worldwide allocates its vast resources to appropriately deliver undivided attention and care to each sponsor. Every Worldwide project is overseen by its Bioanalytical Study Managers (BSMs), who serve as the primary point-of-contact for the bioanalysis. The BSMs work with clients from the initial stages of their programs all the way through to the final reporting of data. If method development work and procuring of reference materials is needed, the BSMs collaborate with the method development team to obtain materials and set a timeline for ensuring that methods are developed and validated within the client's timeline.

The BSMs work with multiple teams and individuals, both internally and externally, throughout study conduct. Internally, this typically includes project managers, early phase clinical site, sample management, laboratory analysts, study coordination, pharmacokinetics, data management, biostatistics, and document coordination teams. Externally, many of the same apply, depending on the various vendors selected for each study phase, and can also include animal facilities and central laboratories. "The BSMs will facilitate and communicate across the various teams to ensure the flow of studies and timely delivery of data and reports. They also look into the quality of data by conducting full reviews for each of their studies prior to submitting the same to our quality assurance team," details Zhou, before adding that the BSMs are in constant touch with clients to provide updates and details in the conduct of their studies. They also regularly participate in client audits and visits to the bioanalytical facility.

Also worth mentioning is the technology investments made by Worldwide, with regard to data analytics. Although most CROs leverage data analytics during stages such as drug development planning, trial insights, and design, and regulatory consulting, Worldwide is different because it is "recognized in research" and it puts patients and data quality first. "We put our money where our mouth is. We also have an unwavering commitment to methodological rigor," adds Zhou.

Worldwide goes beyond the standard oversight offered by alternative CROs for clinical trials. It does so by leveraging partnerships for optimal trial oversight, reporting, and compliance success. This allows Worldwide to effectively manage large amounts of data, which is essential to study success. This best-of-breed technology approach enables the

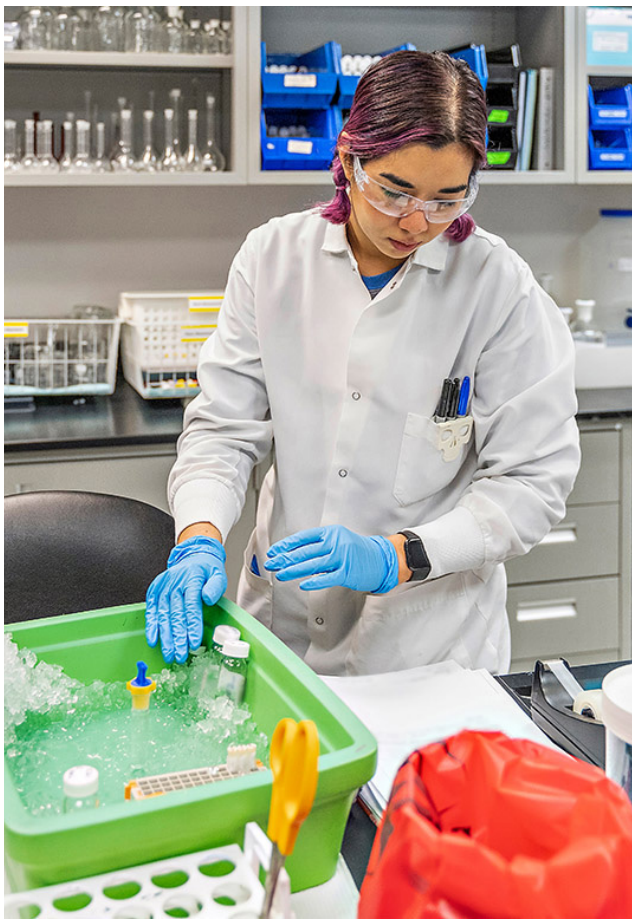


CRO to accommodate preferred partnerships and integrate enterprise systems that span multiple studies.

Delivering Real World Evidence Data

While some CROs specialize in earlier phases of clinical trials, others have access to specific patient groups to test a particular specialty of drugs upon. Worldwide, however, boasts of the expertise, the resources, and the technology to excel across all stages of clinical trials. This is particularly evident in the way Worldwide tackles various challenges as it pertains to helping a client launch a newly-approved drug into the market.

Worldwide offers customized Phase II-IIIB clinical trial services, which can be deployed on a standalone basis or as a full-service solution. The services create scalable, flexible programs based on experiences from other programs—across therapeutic areas—that help in avoiding pitfalls. Phase II-IIIB is often scrutinized for potential trimming to shorten timelines or to reduce the level of investment necessitated by a need to dose range across the fewest number of patients, with disease characteristics that would optimize signal detection. Proceeding with Phase II programs that neither define a clinically useful dose range



nor patient characteristics predictive of response enhances the possibility of Phase III failure.

Understanding the reasons behind product success in a clinic setting and the marketplace is essential. Worldwide specializes in the design of peri-approval studies focused exclusively on this issue. After evaluation of study objectives, Worldwide creates a study tailored to the sponsor's needs, enabling them to consider drug efficacy in treating additional indications, support promotion claims through publication data, or evaluate their product versus a competitor.

Additionally, the Worldwide Evidence practice documents the clinical, economic, and humanistic value of innovative drugs and devices before and after product approval and launch. With "uncommon" technical expertise and decades of practical and strategic perspective, its experts work to objectively and credibly establish evidence of value in actual practice (real-world) settings, using operational techniques that increasingly embrace advanced technology.

Sixty Countries, Same Standard of Excellence

It is evident that Worldwide's ability to provide and manage a sponsor's "resources"—from discovery to commercialization—places the CRO in a class by itself. All the more impressive is how Worldwide maintains a benchmark of excellence across the 60 countries where it navigates through various regulatory requirements and local standards of practice.

To sustain the same standard of services across continents, Worldwide follows a methodology that comprises the strategic direction and framework of how the CRO operates. The daily activities and processes—designed to reflect medical and scientific expertise—live under these core set of standards. The methodology improves the chances of trial success by:

- using best practices as the foundation for operational excellence, optimizing processes driven by lessons learned to maximize success
- following a clear, repeatable, and consistent process
- efficiently and collaboratively planning each project, aligning expectations and goals from the start
- enhancing delivery from Launch through Close-out, getting it right the first time
- managing and communicating risk throughout the project
- providing teams with a central knowledge base to stay up-to-date

Steering ahead, Worldwide will continue to abide by its strong principles, and "never compromise on science or safety" regardless of the urgency or magnitude of a clinical trial. The CRO plans to keep pace with emerging regulatory challenges, technologies, and therapeutic areas, as evidenced by its active participation in biotech conferences and summits across the world. In fact, Worldwide constantly collects survey inputs from biopharma and pharma leaders to further evolve the CRO-sponsor partnership.

To remain at the forefront of its dynamic industry, Worldwide swiftly responds to changes in the regulatory landscape by revising its SOPs and amending its bioanalytical practices where needed.

Worldwide achieved a noteworthy breakthrough recently when it implemented SISCAPA methodology (which provides high selectivity and specificity along with multiplexing) to determine multiple protein concentrations in target tissues."We always stay alert to the newest technologies and challenges in the bioanalytical industry, such as measuring proteins for immune and gene therapeutics," concludes Zhou. Ph

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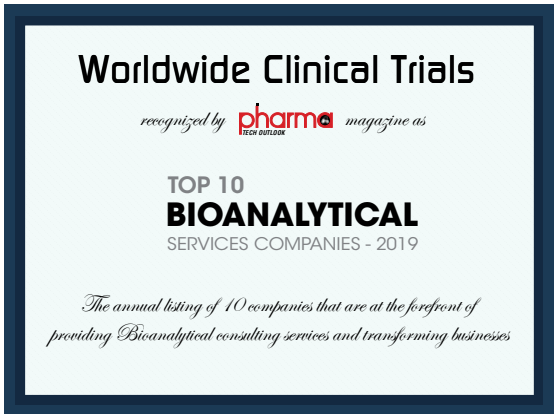
Top 10 Bioanalytical Services Companies - 2019

The rising number of chronic diseases and their immense cost burden on healthcare systems is creating the need for personalized, innovative medicine and drugs in the market. This growing need for new drugs has resulted in an increase in R&D investment by biopharmaceutical companies. However, the pharma and biotech industries are under tremendous pressure to maintain consistent innovation in less time, using fewer resources than before. To that end, companies in these industries are looking for effective partners who can help them accelerate their journey toward new breakthroughs in drug development. With expert partners on their side, the pharma and biotech firms can use their internal resources for more value-added tasks and drive the business outcomes.

Aligning with the latest compliance regulations in the industry, bioanalytical services companies can serve pharma and biotech firms of all sizes in the areas of drug development at both preclinical and clinical stages. The pharma and biotech companies can outsource testing to efficient contract research organizations (CROs) to curtail operational expenditure costs and propel market growth over the forecast period. With in-depth knowledge of using cutting-edge analytical tools, the CROs can play a central role in the inspection, verification, testing of the various biomarkers and molecules. Using industry best practices and experience, the CROs can boost the confidence of the drug manufacturers in releasing their products to the market faster and maintain an edge in the market.

We hope this issue of Pharma Tech Outlook helps you build the partnership you and your firm need to enable technology-driven bioanalytical services.

We present to you Pharma Tech Outlook's "Top 10 Bioanalytical Services Companies 2019."



Company:
Worldwide Clinical Trials

Description:
From early phase and bioanalytical sciences through late phase, post-approval and real-world evidence, Worldwide Clinical Trials provides full-service drug development services for sponsors focused on central nervous system, cardiovascular, metabolic, general medicine, oncology and rare disease therapies.

Key Person:
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