

CAS IP SERVICES℠ CASE STUDY

iUVO BIOSCIENCE USES IMPROVED DATA TO ACCELERATE PRODUCT DEVELOPMENT FOR CLIENTS

iUVO Partner Research Organization

CAS
A division of the American Chemical Society

Solution in brief

iuvo BioScience, of Rush, NY, provides comprehensive research services for pharmaceutical and medical devices companies worldwide. iuvo teams up with CAS IP Services to achieve its mission of helping clients move new products from research to release faster and at a lower cost.

iuvo relies on data from CAS scientific and intellectual property searches to help their clients drive decisions in preclinical research, toxicology testing, and regulatory submissions. The data from CAS forms a cornerstone of understanding for iuvo in developing products and materials and aids in shaping its preclinical strategies.

Quality searches with reliable results give iuvo scientists the confidence they need to support lead compound selection with the greatest potential, shape preclinical research strategies, streamline toxicology testing, and design testing studies that are less complex and therefore less expensive for its clients.



The challenges

Contract research organizations managing client programs for drug and medical device development often find themselves in unchartered territory. A proliferation of new technologies, plus frequent changes in global regulations and industry standards, challenge scientists to navigate an increasingly complex information landscape in designing new approaches for research and testing.

iuvo, Latin for "to serve," navigates these challenges on behalf of its pharmaceutical and medical device clients around the world. The company provides preclinical testing, clinical research, production support, and related services that help clients move new products from research to release faster and at lower cost.

"iuvo's mission is to provide quality advisory services and testing solutions that accelerate the success of our clients and improve people's lives globally," said Mary Richardson, Ph.D., DABT, chief scientific officer, and executive vice president of iuvo.

To fuel its research, iuvo relies in part on data from outsourced scientific and intellectual property searches. If critical data is missed during a search, iuvo's preclinical research, toxicology testing, and regulatory submissions can be at risk.

"In the past, some of the searches we outsourced came back with key references missing, which could lead us to miss positive or negative results on a toxicology endpoint," Richardson said. "Complete and thorough search results give us greater confidence in shaping our decision to proceed with particular compound or in designing a given testing strategy. They also help us refine research strategies to avoid unnecessary testing and costs for our clients."

Comprehensive searches are especially important to researchers challenged by keeping up with the growing complexity of the healthcare landscape.

"With the growth in medical technologies, we rarely get involved with traditional, small molecule testing these days," Richardson said. "What used to be exceptions, such as gene therapies, probiotic drug delivery, and nutraceuticals for chronic diseases, are now the norm and comprise much of our new business."

Regulations for toxicology testing and other research have become equally challenging. "Although there are international guidance documents intended to standardize testing approaches, our scientists still need a comprehensive understanding of the regulatory and testing landscapes unique to each country and scientific domain," Richardson said.



Mary Richardson, Ph.D., DABT
Executive Vice President,
iuvo BioScience

The solution

To ensure its researchers have the highest quality data to succeed in these complex technology and regulatory environments, iuvo turns to CAS IP Services for scientific and intellectual property literature searches. In the past decade, the two organizations have collaborated on more than 40 projects in drug discovery, preclinical research, clinical trials, toxicology studies, regulatory compliance, and product safety monitoring.

Much of the work CAS performs for iuvo involves searching published literature for information about known substances and how they interact, which enables iuvo to make better decisions about what types of toxicology testing to perform in meeting safety and regulatory requirements.

"Information provided by CAS forms a cornerstone in our understanding of the products and materials we develop, and it aids in shaping our preclinical strategies," Richardson said. "We use the CAS data to help clients select lead compounds with the highest potential and avoid suboptimal compounds. We also use insights from CAS searches to eliminate unecessary testing, so we can design studies that are less complex and therefore less expensive for our clients."

Partnering with the search experts at CAS allows iuvo to save time and reduce costs, compared to building and managing a specialized search organization in-house. "Our goal in partnering with outside companies is to choose those with the greatest expertise in their respective disciplines which augment our own capabilities," Richardson said.

This search expertise is especially important as national health authorities exercise greater scrutiny over data and literature citations in evaluating the rigor of searches performed for submissions. "Health authorities require companies to use qualified information specialists to perform these searches, and while they do not define what 'qualified' means, we do not consider ourselves fully qualified in that area. That's why we turn to CAS," Richardson said.

Another benefit of working with CAS is the direct collaboration iuvo researchers have with CAS searchers. Close communications between project team members is critical as iuvo enters new areas of research or when projects take unexpected turns (see sidebar). "CAS searchers have a deep understanding of multiple scientific domains, search strategies, and search resources, and working directly with them lets us more quickly decide on the best course of action and make adjustments as projects change," Richardson said

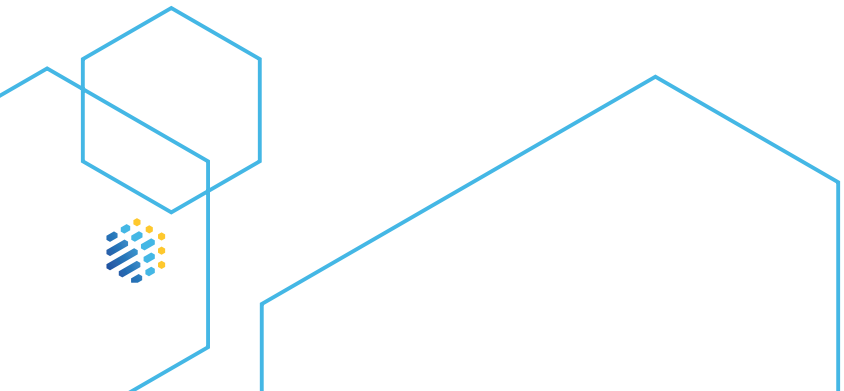
Ready for new challenges

The global research environment for drugs and medical devices continues evolving as new technologies come are introduced, national health authorities collaborate around common regulatory frameworks, and industry standards, such as ISO 10993–1, are modified to improve safety outcomes. iuvo's expertise in managing these changes are a key reason companies will keep choosing it for research services.

"Our clients' information needs change as testing and regulatory requirements evolve and expand, and it's our responsibility to help them address these changes efficiently," Richardson said.

Within this dynamic environment, CAS searchers will support a growing range of initiatives, helping iuvo scientists validate new experimental approaches, support risk management strategies, and substantiate claims in new regulatory filings.

As iuvo navigates these changes for its clients, it will count on insights from CAS to establish sound directions for strategic planning and research. "CAS brings us a higher level of scientific knowledge and is able to design and execute very sophisticated search strategies, which gives us greater confidence in their results. Working with CAS IP Services has been a great partnership, one area in our work that we never have to worry about," Richardson said.



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>
> Mary Richardson, iuvo BioScience

Use case: Close collaboration on data searches reduces time and cost of drug approval

Managing complex preclinical research projects through unexpected changes is a hallmark of the collaboration optimized by iuvo and CAS over the years. The two organizations recently teamed up to meet an urgent regulatory demand for toxicology data required to move a new ocular drug to the next phase of clinical trials.

After submitting toxicology data to a foreign health authority, iuvo received a request from the regulator for new data to qualify a leachable compound used in the drug.

"The request came late in the project and was submission-impacting for our client, with the potential to stop the clock on the regulatory process," said Richardson." We determined we would need to conduct more testing, but the authority came back to us on the Friday before a major holiday, and they wanted a response within 15 days, so we had a very short time to respond."

The iuvo team quickly formulated a response that would require a battery of new tests: additional rapid on-eye testing, ocular irritation testing, and evaluation of the leachable's chemical structure activity for genotoxicity. Still, completing those tests and reporting the results in just 15 days would be challenging, would cost iuvo's client more money, and might delay approval.

In light of these potential implications, iuvo turned to CAS seeking an additional literature search that might uncover data to reduce the need for some of the new testing.

"Our goals for the literature search were twofold: First, to look for any safety data or toxicology that could reduce testing, and secondly, to make sure there wasn't any data that conflicted with the safety claims for the leachable at the levels being considered," Richardson explained.

Like most complex search projects, the iuvo request required an iterative approach, with multiple stages of collaboration between team members and mid-course corrections along the way, recalled Anne Marie Clark, Ph.D., CAS senior scientist, who works extensively with iuvo.

"Mary contacted me about her challenges. I researched multiple databases to find the appropriate information and proposed a search strategy that would align with her goals and meet her urgent deadline," Clark said. "We then held a meeting with her client, and pretty quickly agreed upon the precise search strategy.

The extensive CAS information search that confirmed all the safety claims from iuvo's original submission, while turning up no new data that would suggest the leachable was at an unacceptable level. With these results in hand, iuvo was able to resubmit its data within the regulatory window and avoid additional testing costs for its client. Best of all, the new ocular drug moved smoothly through trials and was ultimately approved without delay.



Anne Marie Clark, Ph.D.
Senior Scientist,
CAS IP Services

About CAS

CAS connects the world's scientific knowledge to accelerate breakthroughs that improve lives. We empower global innovators to efficiently navigate today's complex data landscape and make confident decisions in each phase of the innovation journey. As a specialist in scientific knowledge management, our team builds the largest authoritative collection of human-curated scientific data in the world and provides essential information solutions, services, and expertise. Scientists, patent professionals, and business leaders across industries rely on CAS to help them uncover opportunities, mitigate risks, and unlock shared knowledge so they can get from inspiration to innovation faster. CAS is a division of the American Chemical Society.

Connect with us at cas.org.

About CAS IP Services

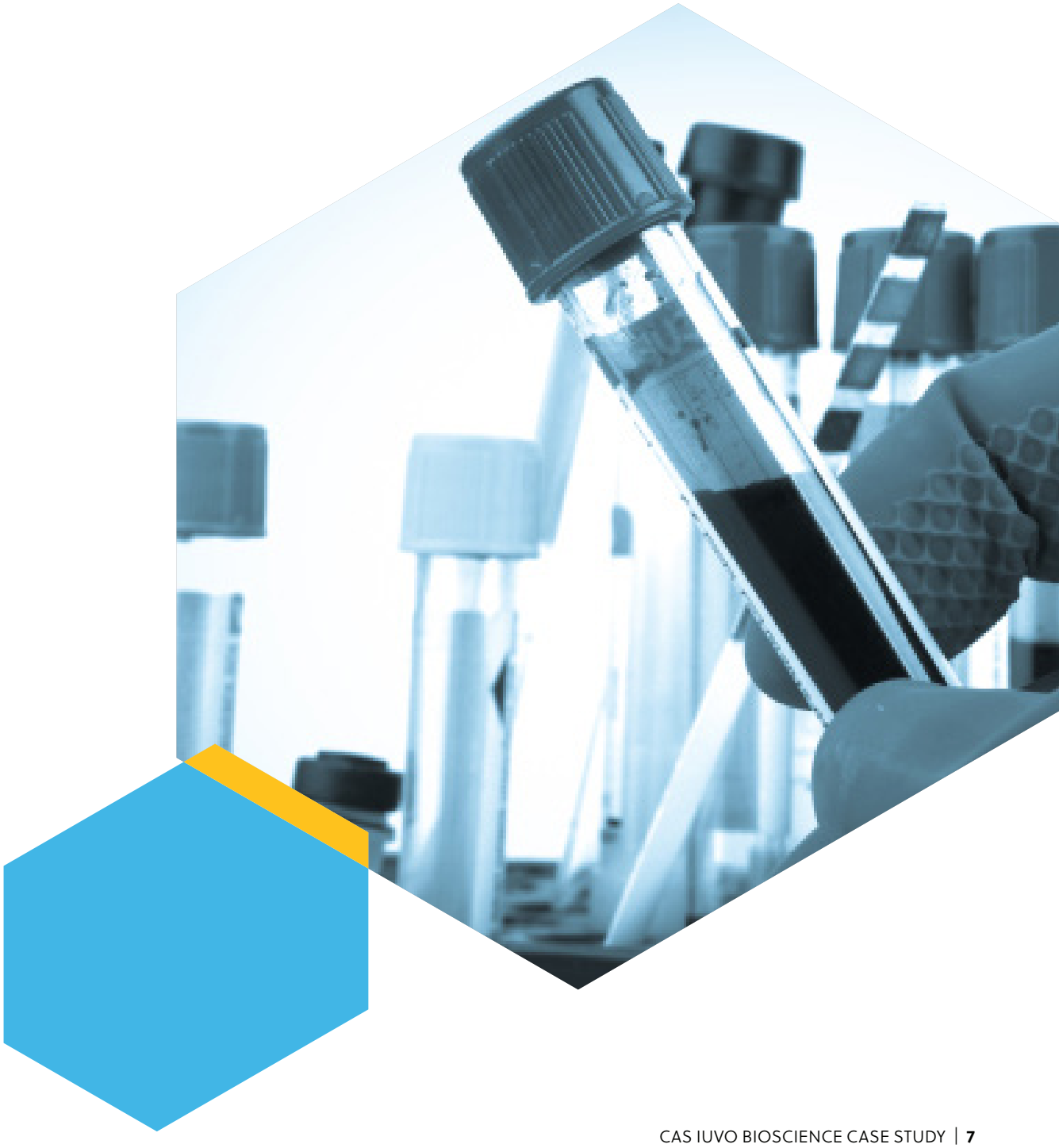
Our team partners with innovation-focused organizations to provide the scientific and intellectual property insights they need to accelerate innovation, protect intellectual property, and make confident business decisions.

- A team of information scientists averaging 25+ years of experience managing and executing search strategies in global R&D organizations
- Direct collaboration with clients to ensure efficiency and project alignment with business goals
- Broad scientific and search expertise:
    - Patent and scientific literature searches
    - Competitive analysis
    - Toxicology and biocompatibility testing
    - Data customization
    - Data analysis and visualizations
    - Regulatory monitoring



About iuvo BioScience

iuvo BioScience is a Partner Research Organization (PRO) serving the medical device and pharmaceutical industries. The company provides contract laboratory services, as well as technical and preclinical consulting from its location in Western New York. The company has extensive expertise in toxicology, analytical chemistry, and microbiology. More information on the company's services and capabilities is available on its website at iuvobioscience.com.





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