

Partnering with CROs

Q&A with Ed Amat, Executive Vice President of Global Sales & Marketing, MPI Research

Contract research organizations (CROs) are playing a pivotal role in new drug development as pharmaceutical companies face rising R&D costs and leaner in-house research departments. Strategic partnerships between drug developers and CROs can dramatically decrease a drug's time to market - according to the Tufts Center for the Study of Drug Development, clinical trials conducted by CROs are completed, on average, 30 percent faster than those conducted in-house. Ed Amat is the Executive Vice President of Global Sales & Marketing at MPI Research and is well versed in the CRO partnership arena. We sat down with Ed and asked him to share his insight on CRO partnerships in today's market, and explain the company's technology and how Sponsors can make the most of their collaborative approach.

Q: You emphasize, "partnering" with a CRO, and not hiring. Why do you think it's so important to use that term?

A: Because merely "hiring" a CRO as a vendor is a thing of the past for companies that want to get their drugs to market as well and as fast as possible. Partnership is an often-overlooked concept when working with a CRO. Over the past decade, CROs have grown significantly, to become less of a vendor, and more of a collaborator, especially since the market drop in 2008. Though the Sponsor does hire the CRO, the most value is derived when they work together toward a common goal. CROs have talented teams and a wealth of experience from executing a high volume of trials in a variety of industries, therapeutic areas, and work requiring strong scientific expertise.

Q: What can CROs and Sponsors do to really maximize the benefits of the partnership?

A: The best way to build a stronger partnership is through effective communication and transparency on both sides - sharing knowledge and ideas. You must be realistic and clear about expectations to achieve results. That's easier said than done, because with any good relationship, it takes work, commitment, and acknowledgment that you're in this together. We always embrace the fact that the Sponsor is our customer, but to help get their drug to market, we must work hand in hand. The CRO and Sponsor should be comfortable enough to challenge the other to arrive at the best outcome.

It's critical that the Sponsor communicates and thinks of their CRO as a strategic partner, while the CRO must gain trust and be clear about what's expected from both the Sponsor and the regulating agency. A good CRO will define the Sponsor's needs as early as possible because having the information up front saves time and helps to make accurate predictions.

Q: Is there an ideal Sponsor for a partnering with a CRO?

A: While any Sponsor with time and money constraints can benefit from a CRO, the ideal Sponsor is savvy enough to know they need help beyond their ability, to choose their partner wisely, and to trust that the CRO has their best interest in mind. Again, communication is the bedrock for success and a major part of the communication is co-developing accurate outlines and procedures, as well as streamlining development. I get that pricing may be the most scrutinized aspect of choosing a CRO, but if that's the main selection criteria, the relationship is built on sandy ground.

Q: *Outside of the traditional CRO science, expertise, and experience, what else does MPI Research offer that would be appealing to a Sponsor?*

A: As with any strong partnership, you need to be together ... and I mean literally! We encourage Sponsors to be on-site as often as they see fit. Our dedicated team of Sponsor Service professionals customizes each visit, securing travel and hotel accommodations, arranging personal transportation to and from our facility, scheduling tours, and securing private on-site audit rooms. From the moment we pick our Sponsors up at the nearby airport, to the delivery of the final report, our Sponsors are our number one priority. Visiting our facility is critical to working with us (either as a prospective Sponsor or a current one), and we make it easy and convenient for you to get here and get home, as we understand the demands on your time.

Q: *We've discussed how CRO-Sponsor relationships are evolving. How does the pharma industry as a whole benefit from the CRO-Sponsor partnership?*

A: When there is real collaboration between CROs and Sponsors, the industry benefits because we get more efficient trials from valuable research. This results in more effective drugs arriving on the market sooner, which in turn, contributes to a healthier world. That sounds trite, but we've seen it, and it's the most inspiring thing for our employees ... at some point, our work is eventually going to help someone with serious health needs. Not everyone can say that about their job.

Q: *Are certain CROs more adept at handling certain types of trials?*

A: Yes, different CROs are certainly more effective at handling different trials, depending on their experience, talent, and facilities. Some smaller labs do offer niche areas of unique expertise. Our core strength has always been comprehensive drug safety assessment, medical device evaluation, and analytical sciences. In addition, our Translational Imaging Center is an example of a specialized resource we have at MPI Research. We offer the

world's only commercially available facility with a dedicated cyclotron, advanced informatics, radio-labeled imaging, and an on-site vivarium. This enables us to handle a variety of different needs for our Sponsors, making development more efficient while lowering costs.

Another key offering that our Sponsors can take advantage of is our clinical research services, at Jasper Clinic - a 50-bed clinical trial unit capable of Phase I and IIa trials. The clinic has a solid reputation among the industry and community for handling adaptive design and traditional studies. The acquisition of the clinic was an important step for MPI Research, as we've become a trusted provider of early-stage drug development for our Sponsors.

Q: *How can you help Sponsors with special circumstances?*

A: We know the right questions to ask because of our vast knowledge and experience. With our insight and expertise, we'll make recommendations based on each individual Sponsor. That's our job... to find solutions. And that's not just about science, it's about drug development and working with regulatory agencies. As a true partner, we're invested in the programs of our Sponsors, and do what we can to maximize their potential while remaining cost-effective. A Sponsor's success is our success and in the rare cases that we don't have the answers or capabilities to support a project, we will guide them to the experts that can help.

Q: *How does MPI Research approach study design?*

A: There's no 'one size fits all' solution when it comes to study design. Our flexibility is critical, and it allows us to work with companies big and small in a variety of different fields. Simply put, we approach every study uniquely because no study is exactly the same. We work with our Sponsors to identify a design that will produce the data needed to continue the development of their drug or device program. With our robust historical data

library, we develop a study design that supports the sponsor's goals and budget. It's at the core of why we emphasize collaboration. Our internal expertise is the difference. We're not just contract research, but a partner advising the Sponsor on how to best meet their drug development goals. They rely on us with our world-class scientists to make a study the best it can be.

Q: *What do you think a Sponsor should look for in a CRO?*

A: Great customer service and great science, based on mutual trust and the best communication. When a drug developer looks for a strategic partnership, it should begin with visiting the facility and meeting the people with whom they'll work. We understand that bids are an important part of the decision making process, however, a CRO should be more than just a bid, it should be an extension of their company.

A CRO has to stay up-to-date on regulatory requirements, and should have a track record of meeting filing goals. Because things don't always go as planned, a drug developer needs a CRO that's navigated through difficulties to arrive at a successful submission.

Additionally, Sponsors should look for a partner that understands and values animal welfare and its impact on study results. Animal welfare is about a lot more than just providing a safe environment and good nutrition; it's about providing the best husbandry available so that the animals experience the least amount of stress and the best possible health. With expertise in rodent and non-rodent trials, CROs must take the lead in developing humane endpoints.

I also think that one of the most important and undervalued things to look for is a personal connection to research. This goes far beyond a mission statement. It's about whether the company is committed, through its actions, to timely reports (which is a given).

Here's an example: Matt and Lori Sames came to us after their daughter, Hannah, was diagnosed with a rare genetic disorder called Giant Axonal Neuropathy, or GAN. The degenerative disease slowly takes away a person's ability to walk, use their hands, speak, and swallow, and is usually fatal in the early 20's. There are approximately 25 diagnosed cases in the world. Because of the dire nature of the disease, our scientists raced to find a gene therapy treatment for Hannah and others suffering from GAN, and were given FDA approval to begin human trials in 2014. I'm also proud to say that MPI Research employees banded together to participate in a Pepsi-sponsored challenge that raised \$250,000 for the GAN charity, Hannah's Hope.

Hannah visited MPI Research in 2012 to meet the scientists and employees working on her treatment. She and her family spoke to us in our auditorium — it was standing room only with few dry eyes in the house. It's not often that we meet the patients we're working to save, and Hannah touched everyone at MPI Research.

Her story is a constant reminder of why we do what we do every day. We want to help people in need, and our team is passionate about doing so!

Closing Thoughts

Regardless of a company's size or development timeline, Sponsors should collaborate with CROs to take advantage of their vast knowledge and expertise in research, trial design, and IND submission. Partnering with a CRO can not only improve an individual drug's time to market, but also ultimately benefit the pharmaceutical industry as a whole through better science and more efficient discovery of life-changing therapies.

To find out how MPI Research can be your strategic contract research organization, visit mpiresearch.com



Ed Amat, BS, is the Executive Vice President of Global Sales and Marketing for MPI Research. Before joining MPI Research in January of 2010, Mr. Amat spent 20 years at Pfizer in various leadership roles where he was recognized with multiple sales and leadership awards. His extensive pharmaceutical career has also included serving as Director of Business Development for a national pharmaceutical contract sales organization, and principal owner of a medical testing company. He received his BS from Western Michigan University and was a member of the WMU Honors College.

About MPI Research

MPI Research Inc. is a full-service CRO located in Southwest Michigan. As a company, we look to develop partnerships that will achieve our Sponsor's regulatory needs. Contact us at info@mpiresearch.com to learn how we can take you further.

MPI Research

Corporate Headquarters
54943 North Main Street
Mattawan, MI 49071 USA
Tel: +1.269.668.3336
Fax: +1.269.668.4151
info@mpiresearch.com
www.mpiresearch.com