

February 2017

Pharma **VOICE**

THE FORUM FOR THE INDUSTRY EXECUTIVE

CEO Insights: Leading Through Extraordinary Change

THE CREATIVE PROCESS

CANCER IMMUNOTHERAPY

RARE DISEASE DAY

DISEASE STATE: ZIKA

SHOWCASE FEATURE

Outsourcing



Smart WILL WIN!

The more this industry changes, the more it stays the same. The companies that apply their intelligence to winning the transactional nature of our business will ultimately succeed. Whether you study the pharmaceutical and biotech industry from the top down or the bottom up, you will find that applying the good business principles that have existed for decades is still necessary for success:

Conduct timely and broad-based market research to segment your customers

We have to remember that we are in business. While the transaction for most of us is a recommendation by an HCP to get a prescription filled, and not a sign on the dotted-line contract, the same principles of sales still apply. You have to decide where you are going to open up your “stores,” or what we call sales territories. Not all towns/cities/states are the same in our business. You will not know how the market in each of these localities will accept and react to your brands until you put in the work to conduct solid market research. I am not saying you need to pull in a couple hundred people, sit behind the glass, and listen to them as they hear your messaging, positioning, or pricing strategy. But technology is our friend now, and this can be accomplished quickly and cost-effectively. These insights will influence your decisions much more than being in every city with a certain physician specialty or density. By segmenting your customers, you can build a bottom-up target list and territory alignment that is built on potential for your product, not someone else’s. There are many companies that do this for you, and there are others that help you to do it yourself. I learned what I know about this from Lenny Vicciardo, CEO of Noetyx LLC (www.noetyx.com). We recommend him and his company to most of our clients who don’t already have a targeting optimization partner identified.

Develop an appropriate commercialization strategy to maximize your ability to invest in these costly assets

Having a representative in front of an HCP is still the most effective way to deliver a product message. But is it the only effective way? Absolutely not. Technology has become our friend, and opportunities exist to find new and unique solutions to get your brand messaging to targeted HCPs. Most organizations have tactically used teledetailing platforms,

Contributed by



PETER MARCHESINI
Chief Operating Officer
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PHARMA COMMERCIALIZATION IN 2017 WILL BE DOMINATED BY TWO BIG IDEAS AS PRICING PRESSURES CONTINUE TO MOUNT: EFFICIENCY AND ACCOUNTABILITY. THIS EMPHASIS WILL CREATE OPPORTUNITIES FOR INNOVATION IN OPTIMIZING YOUR SALES FORCE.

certainly for white space or leave of absence (LOA) territories, but how do you use it to make your most effective assets even more effective? Create a collaborative solution that takes $1+1=2$ and makes $1+1=3$ or more. An entire article could be written on this subject, but there are companies that are already doing this. We are currently exploring other avenues including one by a company we collaborate with, The Perpetual Ideation Machine (PIM) (www.perpetualideationmachine.com), and an innovative product called EMBED. I have asked Philip Storer, Innovation at PIM, to spell out this creative idea we will be piloting with a few of our sales teams in 2017.

Storer says: *“Pharma commercialization in 2017 will be dominated by two big ideas as pricing pressures continue to mount: efficiency and accountability. This emphasis will create opportunities for innovation in optimizing your sales force. Let’s look at the facts: 62.5% of the nearly \$71 billion being spent on commercialization is on detailing physicians whose accessibility rate has dropped from 47% to 44% in the last 12 months alone. The situation is even more dire in specialties where we see much of the growth in pharma. For instance, only 27% of oncologists — a breathtakingly small number — are*

accessible to a rep. Pharma commercialization looks a lot to us like the cab industry did to Uber.

These market dynamics are driving our clients to ask a series of the same questions. How do we use the Internet to create a sales force that is on demand, where and when a physician wants them? How do we use technology to overcome access barriers? How do we innovate our way into filling a brand’s white space? How do we optimize the spend on our existing sales force?

These questions led us to the development of EMBED. EMBED places your sales force directly on your website using a powerful and business rule — driven form of live chat. But this isn’t simply compliant live chat powered by call center employees. What makes EMBED truly special is our use of crowdsourcing technology to connect HCPs with the member of your existing sales force who has the capacity to take the conversation. This is rep-to-HCP communication for a new world. Relational. Efficient. Value-driven. On-demand. Anywhere. Anytime.”

There are so many factors to consider when building a high-performing, effective sales team. For purposes of this discussion, and I’ll focus on just a few.

Do you build it yourself, do you outsource, or both?

The right answer is yes. My simple answer from a financial standpoint to an emerging company is that you should not own anything that does not drive revenue during your first three years. And for the things you outsource, retain control. There is a reason why there are so many companies to choose from when it comes to outsourcing. The right partner can help you do more than you can do yourself. If you are lucky enough to have brands with patent protection and perhaps a few different indications, and that are for patient populations big and small, it is your obligation as a business to optimize the return on this potential. A smart outsourcing partner can help you identify the right ways to do this, while allowing you and your company to focus on the strategic things necessary to reinvest your returns. As a provider in this space, we try not to be all things to all people. Sometimes one of our competitors truly is a better fit for a potential client, and sometimes we are. My job is to put my client in the position to reach their maximum success. After all, the clock is ticking, and if we do our job very well they will come back for other opportunities. There is not a cookie-cutter approach that is an optimized solution. Each company and brand has its own pathway to success, and we help them find it, either strictly through our company or through a combination of companies that have specific expertise to drive the optimized

result. Launching a company and a brand is hard. Most struggle and miss their forecasts. Our job is to optimize the brand's potential right from the start. Find a way to optimize each segmented and targeted HCP group. This is done directly or through thoughtful collaborations with other service providers or other pharmaceutical and biotech companies. A good partner will help you put this puzzle together. If it takes you six to nine months to reach an identified group, it is too late.

Hire talent based on your specific needs, not what you had or did at your last company

It is hard to find the right talent without pressing the easy button. Having built many teams, you find that there is no substitution for hard work. However, all too often we are asked to hire people who worked for this or that pharma company. Sometimes you will have success doing that, however, there are no wrong answers, just levels of being right. If you have not been out in the field with a rep in the last nine months, your understanding of the brand experience of the HCP and the patient is flawed. The coordination that has to occur from the top down and the bottom up in a pharmaceutical company is as complicated

as ever. The skills needed by a representative to sell for a one-product start-up organization is much different than being representative number 397 for a larger sales force. Through your recruiting efforts you need to develop the profile you need to compete with your brand(s). Do they possess the necessary traits and attributes to lead at this company this year and beyond, or are you paying for past success based on a totally different situation? Make sure they pass the "here and now" question.

Pilot new ideas and be opportunistic in finding prescriptions.

Your product may have several indications. Are you getting your fair share of business with each of them? If not, how can you?

Have you asked yourself the following question? If I captured the entire market for my brand for all of the indications my product has, how much would that be? Your job is to find a way to capture as much of this number as possible, while still maintaining optimized profitability. Anyone can figure out the big circle opportunities and segments. A true partner will help you solve for the small and medium opportunities and understand who and what can get you in front of those HCPs.

A true partner will help you feel and look "bigger" in the marketplace while limiting your spend. Smart wins here too.

A true outsourcing partner has seen it done many different ways and will help you uncover these opportunities together. They understand your pain points and financial pressures and know that their job is to not only keep you in business, but to make you a success.

The world we work in is evolving. Take the time to lift your head up to see these current changes and to look to the horizon at what is coming down the road. While some of the old plays will work, optimizing your results will require you to adapt your business practices to take advantage of what the market is willing to give you and then work toward removing any obstacles in your way to ultimate success. 

*Through outsourced partnerships and internal capabilities, **Alamo Pharma Services** offers pharmaceutical and biotech companies a viable commercial solution partner to either co-market with existing teams or launch a stand-alone team.*

For more information, visit alamopharmaservices.com.



We're revealing a smarter approach to your commercialization needs

Don't let exteriors fool you. Inside this charming Victorian home is a team of experienced pharma veterans who have come together to build exceptional sales forces. We're a professional team that's also approachable, bringing a personal touch to optimizing your outsourcing opportunities.

Visit AlamoPharmaServices.com and let's have a conversation about how we can help you build a strong foundation and structure to tackle whatever commercialization challenges you face.



The place where your company will grow.

The Outsourcing BIG PICTURE

► *More companies are turning to outsourcing partners to tackle many noncore activities, but challenges remain.*

Outsourcing is now firmly entrenched in the pharma industry. While pharmaceutical companies have been outsourcing back-office activities for many years now, they are increasingly turning to external partners for research and development activities that traditionally were retained in-house.

Today, the pharmaceutical and biotech industry has the highest level of R&D outsourcing across all high-technology industries,

according to a recent PwC report. And demand for outsourcing services is increasing, allowing pharmaceutical companies to focus on core competencies.

Other reasons for outsourcing include gaining access to new technology capabilities, faster response time, and improving processes, according to Kalorama Information.

In the past cost reduction was the main driver, Gens and Associates have noted.

Tapping New Capabilities

Resource and cost pressures, combined with the need for specialized knowledge, are increasingly leading pharmaceutical companies to outsource drug discovery activities, such as biology services and lead optimization — the final stage in the discovery process before a compound moves into preclinical studies, according to experts at Kalorama Information.

In parallel, life-sciences companies have been partnering more frequently with academia and nonprofit organizations to bolster drug discovery.

EXECUTIVE VIEWPOINTS



ELAINA N. HAEUBER
Executive Director of
Strategic Operations,
Acurian

THE KEYS TO A SUCCESSFUL

STRATEGIC PARTNERSHIP

The goal should be to create a framework for identifying and collaborating on processes that result in the maximized performance of both organizations. The cornerstones of this framework should be transparency/ sharing of information, commitment of organization leadership to success, and openness in managing and resolving issues. This includes recurring mechanisms to provide information related to changes and trends in capabilities, regional and country experience, etc.; monitoring key performance and relationship indicators; and following a robust risk management and escalation process to ensure accountability.

COLLABORATIVE SUCCESS

Outsourcing partners can implement a robust governance framework with defined remits, to not only oversee the strategic relationship and assess key initiatives, but also match future capabilities with future organizational needs. The PRO should be allowed to evaluate the

pipeline, to facilitate resource planning and availability at the right time. Both parties should work together to ensure management of operational issues at the most appropriate level.



TERRY HERRING
President, Alamo
Pharma Services

UNDERSTANDING WHAT SUCCESS LOOKS LIKE

In my experience the most successful partnerships are those in which there is a clear understanding and consensus around what success looks and feels like. It is also important that there are reasonable expectations around the journey to success, for example, timing and possible hurdles and how to overcome them. Sometimes, even with the very best planning, unforeseen challenges arise. In those instances, it is most important that we've built a true partnership based on trust and mutual respect.

EXPERIENCE COUNTS

The best way we can help our partners is to help shape their thinking up front. Often clients come to us with an idea of how many reps they need. We bring our experience to help our partners to truly optimize their approach and modify quickly to yield the best possible ROI. Through this view of their strategy, we determine the best

promotional levers available through our organization.



PENNY BEMUS
Senior VP, Business
Development,
Dohmen Life
Science Services

CONSISTENCY ALONG

THE PATHWAY

Look for a partner that can work with your organization throughout the development pathway to commercialization cycle. For example, our life-sciences clients, from start-ups to established brands, recognize that building their own complex commercialization structure is a redundancy that adds cost to healthcare delivery and diffuses their attention. We've built a bench-to-bedside outsourcing model that doesn't require the traditional and disjointed use of multiple vendors that are not in direct alignment with the sponsor. It's a new model that aims to reduce risk, cost, and operational complexity.

DIRECT-TO-PATIENT MODEL

Business process outsourcers need to evolve. The traditional model of multiple service providers with disparate services is often rife with inherent conflicts of interest. In the rare disease industry specifically, that model often

EXECUTIVE VIEWPOINTS

allows patients to fall through the cracks from onboarding to ongoing adherence. We advise clients to consider a more holistic, direct-to-patient service model in which the outsource partner acts as an agent of the manufacturer focused on reducing the burden of the disease and increasing therapy adherence through coordinated care, patient education, and data-driven insights. This connects manufacturers more closely with patients and streamlines care delivery and support.



JUDY SWILLEY, PH.D.
Executive VP and
General Manager, Head
of Strategic Alliance
Management,
INC Research

PARTNERSHIP DNA

The partnership approach must truly be part of the corporate DNA of both parties. Fit-for-purpose operating models and a partnership culture designed to drive success of the relationship are key. There needs to be true alignment among both organizations — everyone involved needs to understand why the partnership exists, what the goals are, and the roadmap for attaining success. Transparency is critical, as is appropriate resource allocation for partnership oversight along with an effective governance structure.

COLLABORATIVE JOINT ACCOUNTABILITY

Recognize that a partnership isn't something you outsource. Sponsors need to manage and drive the partnership expectations internally to achieve objectives. Partnerships are collaborations with joint accountability. Ideally a sponsor will "mirror" the CRO's partnership oversight, appointing someone internally with alliance management experience to shepherd the relationship. It's also important to realize good partnerships evolve over time; models change as partners work together to build efficiencies that include shared insights into pipelines and long-term planning.



PAUL HARNEY
VP Business Development
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FOUR KEYS TO SUCCESS

There are four keys to a successful partnership: proactive support, flexibility, communication, and innovation. Proactive support is different from just being responsive, which suggests a passive relationship, so we take initiative to drive success. Flexibility is crucial because the pharma landscape is always changing and only those partnerships that allow for change can prosper whereas rigidity leads to missed opportunities. Thirdly, there's nothing that can replace an open dialogue around the good, the bad, and everything in between. It allows both parties to quickly identify and resolve problems as well as capitalize on opportunities. Finally, innovation is imperative — and often missing — in outsourced relationships, characterized by defined contracts. We never rely on conventional methods. As a partner, the goal is to maximize our customers' success so that means offering innovative strategies and solutions.



STEVE DEVRIEZE
VP, Emerging Biopharma
and Technologies for
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Services North America,
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FOCUS ON BUSINESS GOALS

Seek and consider the input and strategic insights from a partner instead of just looking for bodies to fill a resource gap, this will enable a stronger and long-standing partnership. Overlooking the business goals often results in KPIs that are overly focused on the contract, which is a transactional relationship that delivers only what can be defined in the agreement. Creating a broader set of KPIs that cover things such as innovation objectives and even subjective measures will lead to better overall impact on the market and business alignment.



**EVAN DEMESTIHAS,
M.D., RPH**
CEO, The Medical Affairs
Company (TMAC)

PLAYING AN INTEGRAL ROLE

The most successful partnerships are those where an outsourced team is not viewed as "outsourced," but rather as an integral part of the sponsor company the same as the internal headcount. A leading pharma client of ours shared this view and outsourced a large MSL team to supplement its own expansive internal team, and never referenced nor treated the outsourced team any differently. It was always the collective MSL team; always an inclusive "we" and never an "us" and "them" when discussing mission and goals. This has very deep ramifications in that the outsourced team not only feels fully integrated, but truly valued, enhancing job satisfaction and ultimately yielding positive results. In addition, the most successful outsourced programs are when the sponsor also values the outsourced teams' management and takes advantage of their vast experience, including them in the decision making process that yields benefits for the entire team.



BRION BRANDES
Executive VP, Business
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EXPERIENCE AND

EXPERTISE

Outsourced service partners have the ability to bring value to the partnership in multiple ways. First, the experience and expertise of being involved in similar partnerships over time should allow the service partner to provide a diversity of thought into the solution orientation. The service provider should also be able to think outside its individual service deliverables and bring in third-party solutions where necessary to drive success in the partnership.

The Clinical Trial Process

Partnership with CROs continues to expand amid growth in developing markets and an improving global economy. A 2016 Nice Insight CRO and CDMO (contract development and manufacturing organizations) outsourcing survey found that 77% of companies outsource services or operations to CROs, CDMOs, or CMOs organizations.

Typically, companies are outsourcing a high number of tactical activities. For example, a Cutting Edge Information survey found 83% of the top 10 and top 50 pharmaceutical companies outsource responsibility for clinical data management. Among activities these companies are outsourcing include traditional trial monitoring responsibilities and data management.

Companies are looking for more than to simply lift and shift activities with a majority of pharmaceutical companies (69%) seeking strategic partners, the Nice survey found. Other research indicates that there is an even split between a strategic and tactical approach to outsourcing.

Phase II projects are most commonly outsourced (63%), followed by Phase I activities (58%), preclinical work (53%), and Phase III (51%). Even postmarketing studies have a relatively high rate of outsourcing (39%).

According to a Gens and Associates 2016 survey, Pursuing World Class Regulatory Information Management (RIM), Strategy, Measures and Priorities, regulatory activities that companies most frequently outsource include investigational or new marketing application submission publishing, small maintenance submissions, local affiliate submission publishing, safety case processing, and safety reporting. The survey of 52 companies found that the biggest driver for regulatory outsourcing is deriving greater flexibility to manage spikes in submission volume (86%), followed by a push to improve operational efficiency (82%), with cost reduction being the third highest priority (78%).

Challenges in the Relationship

Despite more companies choosing to outsource, problems with the vendor relationships continue. In fact, a survey of pharmaceutical

R&D leaders found that managing outsourcing was the biggest day-to-day challenge they faced.

Loss of control, IP, and confidentiality remain among the main concerns for companies. Poor communication and cultural barriers are also cited as significant challenges in the outsourcing relationship.

Successful outsourcing relationships require careful planning and selection, continual vendor oversight and evaluation, and resource commitment to managing the relationship.

The Changing Face of Outsourcing

While outsourcing has grown across the industry, there has also been huge consolidation.

Perhaps the biggest CRO/vendor merger of the year was the \$18 billion deal between Quintiles and IMS Health that the two companies described as creating a “distinctive global real-world evidence solutions platform.”

It's likely that during 2017 more alliances, mergers, and partnerships will form as the outsourcing industry seeks to meet the growing demands of life-sciences companies. 