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SpineMark CRO Management: Helping Companies Bring Their Product to Market On Schedule, On Budget and In Compliance

Spine, as a niche field in healthcare, is facing challenges from all segments of the market. Third-party payors are denying, bundling or discounting payments for fusions and treatment of degenerative disc disease, while CMS has launched a 120-day review program for preauthorization of costly spine and orthopedic procedures instead of trying to recover funds from payments. New products with and without evidence to support coverage and efficacy must overcome coding obstacles and ongoing denials of coverage for being "investigational."

Given the above, medical device companies must proactively supply their customers with tools to navigate the current reimbursement climate, including providing utilization review for preauthorization, verification of benefits, outcomes studies to support payor coverage and adjudication expertise. Innovation in techniques and products in the field of spine has been dramatically curtailed primarily by FDA clearance issues which tend to increase costs and delay market entry. Only about 20 percent of clinical trials actually finish on time[1], and those that do may find the FDA is tacking on requirements for post-market studies.

This phenomenon can be devastating for device companies that commit significant amount of resources, including time, talent and money, acquiring promising technologies, engineering them into products and conducting exhaustive pre-clinical studies only to find they fall short of executing a successful clinical trial. The delayed completion of a clinical trial typically results in lost revenue, increased expenses and, perhaps most importantly, a missed opportunity of being first to market with improved products, instrumentations or standards of care for patients in need of such services. One must also consider the consequences of completing a resource, labor-intensive clinical trial only to find the product is not covered by CMS despite FDA approval, as was the case with lumbar artificial disc devices.

Unfortunately, not only is delayed completion commonplace, nearly 80 percent of clinical trials fail to complete successfully[2]. These statistics are undoubtedly no surprise to medical device companies conducting clinical studies as the process is, in and of itself, a trial. A successful design and administration of a clinical trial requires an integrated, multifaceted solution that addresses many different factors, including reimbursement, site selection, regulatory, patient recruitment, data collection, trial management, biostatistical analysis and monitoring.

[1,2] ISASS 2012 Meeting, Barcelona, Spain

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The five most common challenges to overcome or address in clinical trial are the following:

1. **Investigative site selection and initiation —** choosing appropriate sites for a study and tracking their enrollment progress
2. **Patient recruitment and retention** — ensuring patients are aware of the trials being conducted in their community through marketing efforts that are approved by the appropriate regulatory agencies
3. **Investigative site management —** providing sites with the clinical, infrastructure and marketing resources to be successful enrollers.
4. **Pre-and post study reimbursement and payor support** — proactively identifying and addressing potential issues that impact the payment process, and providing responses for attempts to deny due to being a new product (these process would also include developing strategies for facility add-on payments or increased payments to both facilities and physicians) as well as to proactively collect medical data and evidence on clinical, economic, function, patient satisfaction and quality of life outcomes. This information is critical to sales and marketing strategies as well as to securing payor coverage for new products.
5. **Surgeon Training and Certification** – establishing study and ongoing surgeon training programs that address learning curve challenges as well as benchmarks for certification for future surgeon users. A defined, measurable training program must be implemented as part of the commercialization program and future sales and marketing to protect the integrity of the product as well as the outcomes from use.

SpineMark Clinical Research Organization (CRO) Management, a wholly owned subsidiary of SpineMark Corporation, is a vertically integrated, spine-focused CRO founded to address these obstacles to successful clinical trials. SpineMark CRO helps device sponsor companies quickly and properly navigate their product's path to market, under the umbrella of one company providing services to avoid duplication of effort, reduce costs, decrease time to complete the study and get the product to market, while providing the complete coordination of all requirements of a clinical trial.

Proper site and clinical research coordinator selection

For a trial to be successful, the sponsors have to choose the right investigative sites. Top enrolling sites have a few characteristics in common: They have appropriate patient populations, a commitment to achieving enrollment goals and possess the internal resources to manage the trial. It is imperative that sites receive extensive training in the parameters of the study, including adhering to protocol and keeping close communications with the sponsor.

Trial sponsors are realizing that having a qualified clinical research coordinator (CRC) at the site significantly enhances the speed of recruitment, patient retention and the completeness of the site's data. SpineMark CRO carefully recruits, selects, trains and places qualified CRCs. These individuals are

instructed on how to recognize problems early in a trial and make adjustments to ensure small issues do not turn into major delays.

An onsite CRC can also be involved in marketing the clinical trial (a task that most sites fail to do well) while coordinating patient recruitment activities. Studies have shown that 44 percent of people find out about studies through the media or Internet, while only 14 percent receive the information from their physicians[3]. This gap reveals the complexity of physician-directed marketing of clinical research. Experienced CRCs like those selected and trained by SpineMark CRO can help the investigative site conduct patient recruitment activities and coordinate approvals from the sponsor and local institution review boards.

Successful model for physician engagement

Skilled CRCs can only do so much on their own. Participating in clinical research requires a considerable amount of planning, resources and commitment on behalf of physicians and their staff. Most medical practices and facilities simply do not have the appropriate infrastructure.

SpineMark CRO works around this by collaborating with physicians throughout the world to streamline clinical research and offer economies of scale so practices of all sizes and experience can participate in the clinical trial. Through its international network of multidisciplinary spine research organizations (SRO), SpineMark has developed a medical advisory board of leading spine experts who provide participating physicians and hospitals an unprecedented level of support and third-party resources experienced in clinical trial management.

Since there is a growing need for greater transparency in clinical research, particularly in the spine industry, the SpineMark SRO model was developed to provide intermediary third-party oversight to make sure the highest quality of monitoring, surveillance and resources are brought to bear for patients participating in these trials. By working with SpineMark CRO, sponsors take comfort knowing their clinical research satisfies transparency concerns and, through audits by and guidance from SpineMark CRO's expert staff, has a complete overall adherence and compliance to industry best practices, federal regulations and good clinical practice guidelines.

Reimbursement and payor issues addressed proactively

Reimbursement issues must be addressed prior to protocol development for studies. Medical device manufacturers need to understand the nuances of payor coverage and the impact on the successful commercialization of new products as part of their product prototype development plan. Proper

[3] www.ciscrp.org/professional/facts_pat.html

planning should include coding strategies for professional and facility services, competitive market and reimbursement analysis, economic modeling, evidence to support the efficacy and benefits of the product from a financial, clinical and patient satisfaction perspective and training requirements for provider adoption and utilization.

To assist in this process, SpineMark CRO implements payor education programs as part of the launch of any new study. In addition, since reimbursement is typically a regional process versus national, target markets in investigator sites are involved in the education campaign to actively address post-trial coverage issues. SpineMark CRO also offers additional services to support sites undergoing clinical trial activities through a company-sponsored hotline. This hotline is manned by an independent third-party reimbursement expert trained to handle questions or provide services for areas including the following:

- Preauthorization and eligibility of benefits for facilities and physicians
- Payor coverage inclusion and exclusion criteria for local Medicare Intermediaries and other payor groups
- Support for denied or discounted physician/facility claims
- Coding guidelines for physicians and facilities

In addition, using a defined payor education strategy pre-, intra- and post-FDA approval, outcomes data from enrollment will be presented to key insurance carriers in study site markets to launch payor education programs on the medical necessity, cost and clinical benefits, treatment parameters and patient selection criteria for a new product.

Extensive, ever-adapting turnkey solutions

Since every trial is different, and every device company has different needs, SpineMark CRO's extensive turnkey solutions are customized to address the specific requirements of a particular trial and the objectives of the sponsor. Other services provided by SpineMark CRO include outcomes study development and analysis; data management; competitive market analysis; payor education programs; billing and collections; and adverse event handling, if necessary.

While these protocols, process and solutions have a proven track record of success, SpineMark CRO continues to evolve, improve and expand its services based on the results of every new project and partnership. Changes in regulations, the healthcare industry and global economy are also taken into account.

Enrolling patients in a trial is clearly a "make it" or "break it" activity, and one that requires an understanding of how to initiate sites, recruit patients and manage research coordinators. SpineMark

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CRO leverages its experience in working with manufacturers and physicians to conduct successful clinical trials to help new partners meet trial enrollment on time and achieve their ultimate goal of bringing the latest in treatment advances to patients worldwide.

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