

**OPTIVUS<sup>®</sup>**

Saving lives with proton therapy™

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**THE PATH TO PROTONS:  
BUSINESS CONSIDERATIONS FOR A  
PROTON BEAM THERAPY TREATMENT CENTER**

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## EXECUTIVE SUMMARY

According to the National Cancer Institute (NCI), an estimated 1,399,790 people will be newly diagnosed with cancer in 2006—more than half of whom will have cancer of the prostate, breast, lung or colon.<sup>1</sup> Proton beam therapy—first proposed in 1946 as a mechanism to treat cancer by physicist Robert Wilson, PhD—has proven, via decades of clinical trials and positive patient outcomes, to be the most precise, effective and desirable form of radiation treatment for over 50 different types of cancer, including some of those mentioned above. Yet today, only four hospital-based proton beam treatment centers exist in the United States.

With such increasing medical demand—and with over 60 NCI-designated Cancer Centers in the United States—why do so few proton beam treatment centers exist? This apparent divergence between opportunity and implementation is, in large part, due to the considerable resources required to plan, design, and build a proton beam treatment center. However, as proton beam therapy continues to gain positive exposure among physicians, it has moved into the treatment mainstream—and presents an unprecedented opportunity for health-care organizations to draw new patients to their facilities, improve their reputation as a cutting-edge treatment center and, most importantly, effect truly positive outcomes for their patients. By thoroughly understanding the business implications of implementing a proton beam therapy center, health care decision makers can begin to weigh the pros and cons of adding this new treatment option.

## BACKGROUND

Proton beam therapy—first proposed in 1946 as a mechanism to treat cancer by physicist Robert Rathbun Wilson, PhD—is now widely recognized as the most precise form of radiation treatment available for certain types of diseases. In stark contrast to traditional photon (x-ray)-based radiation therapy, proton beams are highly controllable, more effective in destroying diseased cells, and affect less healthy tissue—resulting in better patient outcomes with fewer unwanted side effects.

Since the first patient was treated in 1956, more than 40,000 people<sup>2</sup> have benefited from proton beam therapy; of those, more than a quarter—or 11,300 patients—have been treated at Loma Linda University Medical Center (LLUMC)<sup>3</sup>. Established in 1990, LLUMC's Proton Treatment Center is the world's first clinically

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<sup>1</sup> *Cancer Trends Progress Report - 2005 Update*, National Cancer Institute, NIH, DHHS, Bethesda, MD, December 2005, <http://www.progressreport.cancer.gov>.

<sup>2</sup> *Particles Newsletter*, Number 36, July 2005. [www.ptcog.com/particles/ptles36.pdf](http://www.ptcog.com/particles/ptles36.pdf)

<sup>3</sup> Loma Linda University Medical Center, October 2006.

based program, followed, in the United States, by the Francis H. Burr Proton Treatment Center in Boston, established in 2001 at Massachusetts General Hospital; the M.D. Anderson Proton Therapy Center, established in 2006 at the University of Texas; and the proton treatment center at the University of Florida at Jacksonville, established in 2006. By 2008, the National Association for Proton Therapy expects two additional centers to be on-line—at Hampton University in Virginia, and at the University of Pennsylvania in Philadelphia<sup>4</sup>. In 2006, the four existing centers will deliver around 50,000 discrete treatments to approximately 2,000 patients, with the majority of those occurring at LLUMC.

According to the National Cancer Institute, an estimated 1,399,790 people will be newly diagnosed with cancer in 2006. More than half of these patients can benefit from proton beam therapy. Approximately 2,000 patients will be treated by proton therapy—leaving more than 690,000 patients without access to this treatment modality.

The reasons for this apparent dearth of proton centers are varied. While proton beam therapy is inarguably desirable from a treatment standpoint, the decision to implement a center that uses this technology involves significant financial, physical plant and personnel considerations. With start-up costs of up to \$100 million (including the building and needed support facilities), a proton beam therapy center represents perhaps the most significant capital investment a healthcare facility has ever faced—and raises important questions about return on investment. But, with what promises to be an increasing medical demand for proton treatment options in the coming years, more and more hospitals and healthcare entities will seek to establish one. By understanding the key business issues involved in implementing a proton beam therapy center, healthcare stakeholders can confidently decide whether or not to add this treatment option.

## EVALUATING A PROTON BEAM THERAPY EQUIPMENT MANUFACTURER

During the past 16 years, the proton beam equipment market has grown from one manufacturer to seven—of which three are FDA-cleared providers. Some are established specialists, focused solely on the research of protons and their most effective clinical applications; others are “name brand” healthcare device manufacturers—with whom some hospitals have existing relationships—and who have added a proton beam therapy line to a broad portfolio of equipment. This means that hospitals and other entities considering a proton beam therapy center have a

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<sup>4</sup> National Association for Proton Therapy Web site, <http://www.proton-therapy.org/>.

significant degree of choice in a manufacturing partner—and have a tremendous opportunity to compare manufacturers' capabilities to make the best strategic choice for a long-term partnership. Following are some key considerations when evaluating a prospective proton beam equipment partner:

### Device throughput and reliability

As a healthcare metric, patient throughput is nothing new. The ability to match capacity with demand, as well the ability to understand the effects of throughput variability on cost and quality of care, is crucial to ensure a particular treatment option will be efficient, profitable and capable of meeting patient safety and satisfaction goals. And, with reimbursement rates continually being squeezed, providers face mounting pressure to increase throughput wherever possible.

Throughput is also a critical consideration when evaluating a proton beam therapy partner. As of this writing in 2006, Medicare and private insurance reimbursement rates range from approximately \$950 to \$1,100 per treatment. This means machine capacity should be thoroughly investigated; a difference in throughput between manufacturers can translate into millions of dollars in lost revenue per year—as well as a significant increase in time to ROI. Conversely, high throughput from the first day of operation accelerates the break-even date and increases future revenue potential.

Closely related to throughput is the question of equipment reliability. If a machine is consistently unavailable due to process failure, then capacity, revenue and patient treatment quality are adversely affected. Oncologists who lose confidence in the equipment's performance may cease prescribing proton therapy altogether. It is crucial, then, to ask any prospective proton beam therapy vendor for the following key information:

- **Proven throughput numbers** – Because many proton beam vendors are new to the market, it is common practice to vaguely cite competitors' throughput data as their own. Insist upon demonstrable numbers obtained, consistently and over time, from manufacturers' own systems. Today, the majority of proton patients are treated with a gantry, which has become the standard for proton beam treatment. As such, the ideal metric for comparing a manufacturer's overall system performance is the number of patients treated per gantry per day, for a period of at least 1 year.
- **Equipment uptime data** – Poorly designed, specified or manufactured equipment can result in complete facility downtime. Robust designs must be incorporated into the system to prevent facility downtime that could

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otherwise last days or weeks. Stop-gap measures to funnel patients into traditional radiation therapy are not acceptable due to clinical efficacy and capacity issues, and cause their own set of throughput challenges. Ask prospective vendors to share documented uptime data, as well as information about the average length of time required to execute repairs on failed equipment. Find out if their equipment has failed in a manner such that it became necessary to have proton beam therapy patients moved over to conventional radiation therapy—and if this has happened, inquire how often it happens.

- **Physical plant design** – While space restrictions often dictate the overall footprint of the treatment center, ask all prospective vendors to share their space and shielding requirements. Based upon the size of the actual equipment—including the accelerator and gantries—determine how many treatment rooms can be built. Larger equipment requires more space—resulting in increased building costs—and may adversely affect throughput numbers by limiting the number of treatment rooms and therefore patient flow.

### **Device safety record**

Many medical devices used in the United States must be cleared by the U.S. Food and Drug Administration (FDA). The purpose of this clearance is to indicate that each device has been evaluated against rigorous standards for safety and efficacy, and to ensure continuing compliance with the FDA's quality guidelines (which are specific to each device).

The FDA defines proton beam treatment systems as Class II Medical Devices. As such, these devices cannot be marketed or sold prior to receiving FDA clearance—and proton beam therapy providers cannot bill for, or receive, Medicare reimbursement using established codes until this clearance is granted. This helps prevent several safety issues from occurring, including: unprescribed radiation exposure to patients; physical injury to patients or treatment providers; inadvertent radiation exposure for treatment providers; residual radiation; and equipment damage due to residual radiation.

Proton beam therapy has demonstrated an extraordinary safety record. However, a thorough investigation into a particular device's safety record—as well as the clinical and financial impacts of creating a safe maintenance environment after a system failure—is a prudent part of the vendor evaluation process.

Several key considerations exist for evaluating equipment safety issues:

- **Regulatory Clearance** – It is essential to determine whether a manufacturer is offering an FDA-cleared device, and whether the manufacturer itself is registered with the FDA as a producer of that device.
- **Safety record** – Check a potential vendor’s safety data for any proton beam therapy device under consideration. Determine whether any reportable incidents have been associated with the equipment, as well as how many actual patient treatments have been performed—since safety should be demonstrated over a significant (in the tens of thousands) sample size. Any safety failure undermines physician confidence in the therapy—and places patients at risk. And, negative publicity resulting from an unstable device can be difficult to overcome.
- **Accelerator type** – Two accelerator types are used in proton beam therapy devices. The older of the two, originally developed in 1932, is called a cyclotron. This type of accelerator uses a combination of a constant magnetic field and an alternating electric field in a disc-shaped chamber to generate its beam. The newer-generation accelerator, called a synchrotron, was developed in 1946 and uses an increasing magnetic field in a ring-shaped chamber to guide the accelerated beam.

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Cyclotrons constantly produce high levels of energy that must be degraded to the proper energy and depth in order to treat patients. Degrading the proton beam requires very high beam intensity in order to overcome the significant losses associated with the degradation process. The need for large variations in proton beam intensity means the potential to overdose becomes an increased patient safety factor. Additionally, the residual radiation associated with a cyclotron and energy degrader requires a significant waiting period—sometimes as long as 48 hours or more—before the machine “cools down” and service personnel can enter the room to service the device. Conversely, because of their inherent design, synchrotrons effect their protons’ accelerated energy in a far more efficient manner. This ensures an environment free of residual radiation, where service personnel can immediately access the device for required maintenance.

### **Planning and executing system upgrades**

Because of their extensive—and costly—physical plant and equipment requirements, proton beam therapy centers have expected lifecycles of more than 40 years. Because advances in the field of proton beam therapy are rapid, centers must deploy a modular design to ensure access to the latest technologies

and therapeutic approaches. To remain competitive in this constantly evolving environment, technological agility and the lowest possible device upgrade costs and system downtimes are needed.

Poorly planned and executed system upgrades can result in lengthy clinical interruptions, which decreases throughput and creates logjams for other modalities—many of which simply cannot handle unexpected emergency overflow. This downtime creates potentially dangerous treatment delays and can quickly undermine physician and patient confidence in the therapy. The resulting negative backlash can result in decreased treatment prescriptions and adverse publicity.

Be sure to inquire about the following key information when evaluating a vendor:

- **Proven experience in installing, maintaining, and upgrading the equipment with little to no clinical interruption** – Find out how many proton beam treatment centers a particular vendor has installed and maintained, how long the devices have been operating, and how many upgrades have been performed on those devices. Also determine how many hours, or days, of equipment downtime is needed for servicing, as well as the resulting impact on clinical throughput.
- **Proven commitment to research and development, as well as ongoing equipment evaluation** – Because the field is rapidly evolving, the most desirable proton beam vendors maintain a singular focus on the science—including the most cutting-edge delivery systems and, most importantly, the patients who benefit from their work. Look for manufacturers who have established long-term relationships with their healthcare partners, and who have proactively—over time—collaborated on the development of new technologies. Because this kind of information is somewhat subjective, do not rely exclusively on a vendors' own report. Ask to speak with one or more proton center administrators and/or physicians to gather more information.
- **Demonstrated, proactive consideration of the center's future, with treatment centers designed and configured to facilitate upgrades and expansions** – A modular system design enables easier and safer equipment access and upgrading, since affected components can be handled individually. With non-modular systems, a modification to one component often directly affects other components—which increases the time and costs involved in making repairs or upgrades.

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### Specific expertise in proton beam therapy and ability to serve as a committed business and clinical partner

Although proton beam treatment therapy was first proposed in 1946, its clinical application was—until recently—limited by the equipment. More flexible machines than were traditionally used in laboratories for proton research were required to precisely treat anatomic disease. In 1990, the world's first patient was treated with a proton beam in a hospital-based center. This was the culmination of years of collaborative research and development (R&D), focused singularly on the scientific application of protons in the treatment of cancer.

As is common across all industries, once the clinical application of proton beam therapy was proven, additional manufacturers entered the market to exploit new revenue streams. Manufacturer expertise in proton beam therapy is closely coupled with throughput, reliability, uptime and safety; as such, it can greatly impact a center's reputation and revenue. Due diligence in evaluating a vendor's experience is critical; choosing a strategic partner too soon—only to discover inexperience later, after committing significant resources to the development of a new center—can seriously derail or even scuttle the project.

Key considerations include the following:

- **Specialization** – Determine the focus of the manufacturer. A company's focus and proven track record is the best predictor of their future commitment to proton therapy.
- **Demonstration of second- or third-generation technologies** – Proving throughput, reliability, safety and superior performance without the benefit of history is difficult. Lack of a lengthy equipment track record means vendors must rely on marketing collateral, instead of direct data, to support performance and expertise claims. Request information on the age of any installed devices, as well as the number of times those devices have been successfully upgraded.
- **Patents** – Determine whether the vendor under consideration is a trailblazer or a follower. Manufacturers that hold the first patents on proton beam therapy technology demonstrate a true commitment to specialization and the pioneering spirit required to lead the technology into the future.
- **FDA clearance** – Few proton beam therapy devices have been cleared for clinical use in the United States—though some non-cleared devices are being actively marketed (see above for more information on the importance of FDA clearance).

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### Projected cost

Depending on the type and number of treatment rooms—including patient alignment and treatment options—equipment costs can range from \$20 to \$80 million, not including the cost of a building. For a larger, four treatment room facility, the total implementation cost for a proton beam therapy center can rapidly approach \$100 million. As demand for proton therapy continues to increase, health care decision makers will be facing the strategic question as to whether the value of investing in proton therapy exceeds the cost of losing patients to other regional treatment centers.

The cost considerations for implementation are broad. Some key considerations in evaluating a prospective vendor include the following:

- **Equipment footprint** – Determine the size and weight of the gantry. Smaller gantries require smaller buildings to house them, resulting in less significant physical plant requirements. This also creates flexibility for large urban areas, where space constraints may otherwise prevent the construction of a proton beam therapy center.
- **Proposed facility configuration** – Determine the number of treatment rooms that the physical plant can accommodate. This is a critical question, and is closely related to a given vendor’s equipment footprint. Smaller, lighter gantries also free up space for additional treatment rooms, which positively affects throughput. Higher patient capacity translates into a higher return on investment.
- **Expandability** – Determine system modularity for future expansion capabilities. Based on the local market analysis and/or availability of funds, an institution may opt to begin with a reduced-size and -cost facility, with the goal of adding treatment rooms later as desired.
- **Financing options** – Financing is a key aspect of obtaining a proton beam treatment center. The financing structure may depend on several variables, such as who will own the center, whether the center will be for-profit or not-for-profit, the size and location of the center, the population density and demographics of the region, hospital and physician group affiliation(s) and the bank(s) participating in the financing. Since financing is largely contingent upon patient revenues, a reputable, FDA-cleared manufacturer with a demonstrated high-throughput system that can deliver treatments quickly and efficiently is required. Also, to obtain cost-effective financing, an investment bank with a national presence and knowledge of proton therapy is suggested.

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To the extent that third-party financing in the form of debt or equity is required, an independent feasibility analysis performed by a qualified consultant is recommended. This analysis should include a thorough study of the market area, patient demand, cancer incidence rates and financial projections. There should also be an analysis of potential competitive threats, and opinions certifying the expertise and capability of the prospective vendor to deliver a proton system within the specified construction period.

## **CONCLUSION**

As proton beam therapy continues to gain positive exposure among physicians, it has moved toward the treatment mainstream. However, because total implementation costs (including the equipment and physical plant requirements for a full-scale, four treatment room facility) can rapidly approach \$100 million, adding this treatment option will remain a major strategic decision for any healthcare organization—regardless of determination of need.

Entities that have successfully navigated the needs assessment phase, and are moving toward establishing a proton beam therapy center, face a significant degree of choice in selecting a long-term, strategic equipment vendor. As part of the vendor evaluation process, key stakeholders should ask pointed questions, and demand hard data, in order to confirm a proven, demonstrable track record of safety, reliability, scientific expertise, and continued investment in R&D. Historical success in each of these areas will ensure a fruitful, long-term partnership that will keep the center on the cutting edge of patient care.

## **ABOUT OPTIVUS**

Optivus Proton Therapy, Inc. designs, constructs, operates and services state-of-the-art Proton Beam Treatment Centers for major medical centers worldwide. Optivus' patented, cost effective, turnkey systems provide the highest patient throughput, widest variety of treatments, and highest operational reliability and safety of any Proton Beam Treatment Center. Optivus is the industry leader in client satisfaction, R&D excellence, service and reliability. These qualities are exemplified by Optivus' high-capacity and efficient system at the Loma Linda Medical Center, the only hospital-based system that has delivered greater than 170 patient treatments per day.

## **FOR MORE INFORMATION**

For more on Optivus Proton Therapy's Proton Beam Treatment Centers, please visit [www.optivus.com](http://www.optivus.com), or call (888) PRO-TONS.

## LOMA LINDA UNIVERSITY MEDICAL CENTER PROTON TREATMENT CENTER FACILITY BRIEF

In 1990, Loma Linda University Medical Center (LLUMC) opened the world's first hospital-based proton beam therapy program. Since that date, more than 11,300 patients with over 50 types of cancer have been successfully treated at the center—a number that represents more than 80% of all hospital-based proton therapy patients.

The U.S. Department of Energy's Fermi National Accelerator Laboratory (Fermilab) developed the synchrotron particle accelerator installed at LLUMC in 1990. In 1993, several engineers and scientists on that project formed Optivus Proton Therapy, Inc—LLUMC's strategic proton therapy partner. During the past 16 years, Optivus has performed three major upgrades, and close to 50 intermediate upgrades, to the core technology—each of which was designed to improve throughput, system reliability and clinical applications.

In March of 1998, the center at LLUMC exceeded 100 patients per day with 98% uptime, reaching a high of 173 patient treatments per day. LLUMC anticipates that Optivus' advances in Image Guidance Proton Therapy (IGPT), as well as in FDA-Cleared Intensity Modulated Proton Therapy (IMPT) systems, will soon double that capacity.

Additionally, during its 16 years in operation, LLUMC's Proton Therapy Center has boasted a 100% safety record. "We've had no incidents," says medical director James M. Slater, M.D. "When you consider that we've provided over 350,000 individual patient treatments, the significance of that record becomes clear."

LLUMC has also experienced a consistent equipment uptime of 98%.

For more information on LLUMC's Proton Therapy Center—including information about the Optivus technology that powers it—visit [www.llu.edu/proton/](http://www.llu.edu/proton/) ■