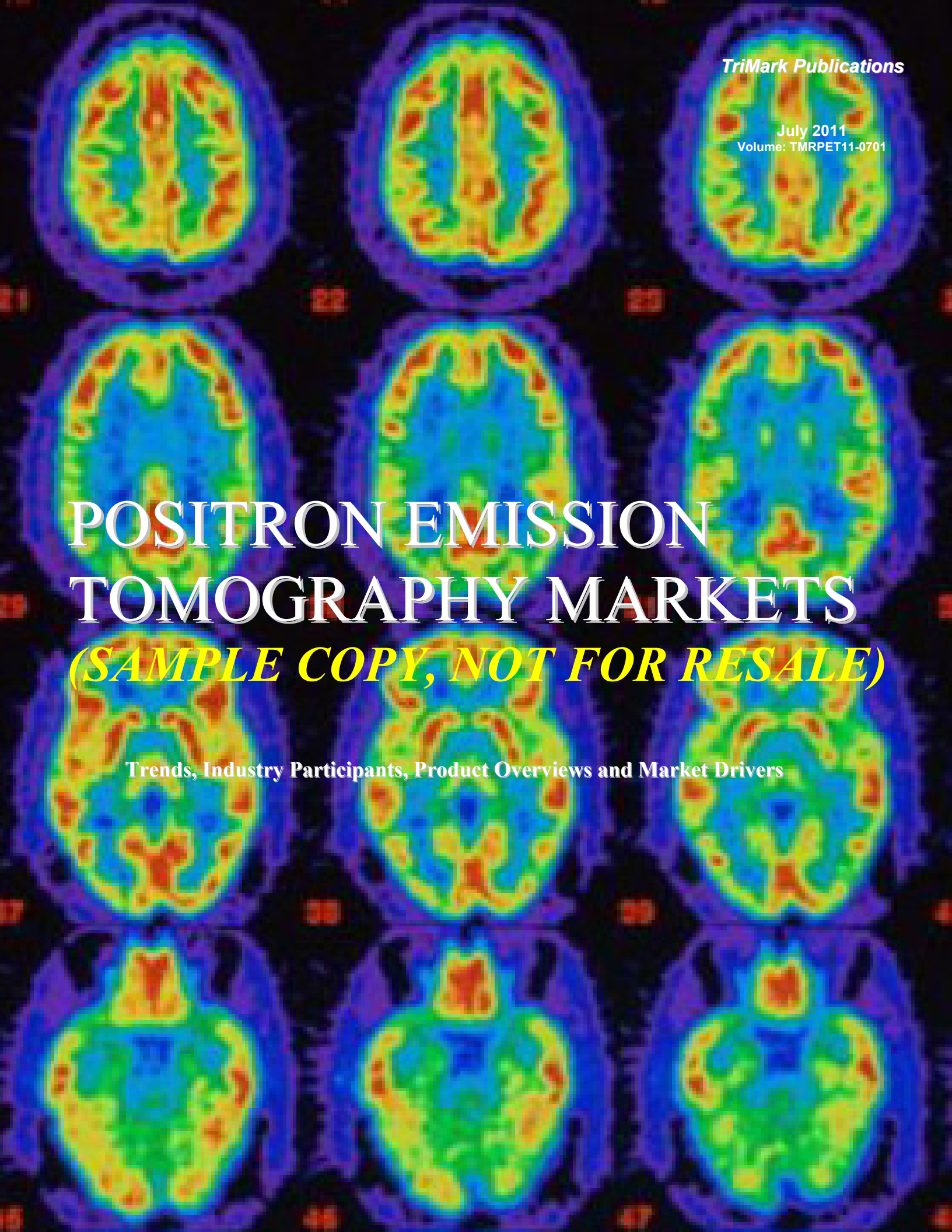

TriMark Publications

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POSITRON EMISSION TOMOGRAPHY MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers

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1. Overview

The medical imaging segments are poised for a major new phase of growth fueled by the availability of new technology coming out of the computer and digital information technology segment. Continuous improvements in technology are resulting in a growing number of new imaging tests that combine high levels of accuracy with rapid, easy-to-use product formats. Part of that medical imaging improvement is coming from positron emission tomography (PET). PET is a scanning technique used in combination with small amounts of radio-labeled compounds to visualize the anatomy and function of the brain.

The purpose of this TriMark Publications report is to describe the specific market segment of the diagnostics medical imaging market called PET scanning. This sector includes all of the generally accepted imaging activities that are currently used in PET, including equipment for PET, PET/CT, SPECT and the use of radiopharmaceuticals for imaging. It examines these clinical measurement devices and their reagents and supplies as used in hospitals and clinics. It also reviews associated clinical market segments in which PET scanning has taken a prominent role including cancer treatment, cardiology, and neurology imaging markets.

PET scanning is the fastest growing medical imaging modality in the U.S. as well as the European and other developing regions of the world. Its principal role has been in oncology, where it has an increasing role in diagnosis, the monitoring of treatment or the progression of disease and in the staging of patients for radiation therapy. Most of the oncology PET procedures are now reasonably reimbursed under Medicare and by insurance companies. Research has proved the effectiveness of diagnostic applications in cardiology and neurology and reimbursement as clinical procedure is expected soon.

Growth of the PET market from its clinical beginnings in the early 1990s has been rather impressive, but it has been hindered by the non-availability of the radiopharmaceutical required for imaging. As the physical half life of ^{18}F (FDG) is short (110 minutes) and as it has to be generated using a particle accelerator (*e.g.*, cyclotron), each PET scanner is required to be in close proximity to a commercial PET radiopharmaceutical manufacturing facility that costs $[redacted] to $[redacted] to construct. Consequently, clinical PET is usually available only in big cities where a radiopharmaceutical manufacturing facility can offer its radioisotope to a minimum of [redacted] or [redacted] PET scanners. Commercial PET radiopharmaceutical manufacturing, and to some extent PET scanning itself is not a profitable business in a geographical region with an accessible population of less than [redacted].

The recent PET scanners available in the market are made up of a large number of detectors arranged on numerous rings and are able to identify pairs of 511 KeV photons emitted at 180° to each other which are formed following the annihilation of a positron when it meets an electron. In a PET/CT hybrid scanner, the PET and CT tomographs are placed in a single gantry with a single patient bed and workstation. PET/CT scanners can also be used either as a dedicated PET scanner or as a dedicated CT scanner. On reconstruction, both the PET images and the CT images can be viewed side by side and overlaid. PET/CT brings together functional (PET) and structural (CT) information into a single scanning session, enhancing lesion localization and interpretation accuracy. Presently, PET/CT is the most advanced technique of metabolic imaging and the most efficient tool for tumor staging in the pretreatment, post-treatment and follow-up phases. Technological improvements of PET/CT scanners are anticipated in the near future with an improvement in the efficiency of detector crystals, the spatial resolution and a reduction in acquisition times of the emission images.

1.1 Scope of This Report

The main objectives of this report are to:

- Identify viable technology drivers through a comprehensive look at various platform technologies for PET.
- Obtain a complete understanding of the use of PET—predictive, screening, prognostic, diagnostic and monitoring—from its basic principles to its applications.

- Discover feasible market opportunities by identification of high-growth applications in different imaging areas, with a focus on the biggest and expanding markets for PET.
- Focus on global industry development of PET through an in-depth analysis of the major world markets for medical imaging, including forecasts for growth.
- Establish the essentials of the PET imaging market including definitions, processes and trends.

Market figures regarding the current value of the medical imaging market are taken from the most recently available data of the global medical products industry. This report covers the following categories of medical imaging:

- PET.
- PET/CT (computed tomography) combinations.
- SPECT (single-photon emission computed tomography).
- Radiopharmaceutical imaging.

Analysis of PET scanning includes the use of charts and graphs measuring product growth and trends within the marketplace. In addition, a discussion of research into the medical imaging arena provides the reader with a deeper understanding of the possibilities for future treatment and avenues for possible R&D budgets. Company-specific information, including sales figures, product pipeline status, and research and development trends, is provided throughout the report. The study will:

- Assess the PET market drivers and bottlenecks, from the perspective of the medical and scientific communities.
- Discuss the potential benefits of the PET market for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the PET market and analyze the current size and growth of various segments.
- Provide current and forecasted market shares by company.
- Discuss profit/business opportunities by imaging segment.
- Provide strategic recommendations for near-term business opportunities.
- Assess current commercial uses of the PET technology platforms.
- Review the PET business models.

PET products consist of hardware, software and supplies used to create, view and manage visual images of non-visible organs of the human body for purposes of research, diagnosis and guidance of non-invasive surgery. This report will focus on end-user markets including hospitals, research facilities, freestanding clinics and equipment-leasing companies. In the past few years, several multimodal products have been developed in an attempt to combine the advantages of structural and functional imaging. Multimodal combinations discussed in this study include:

- CT/SPECT units.
- CT/PET units.

The emphasis in this analysis is on those companies that are actively developing and marketing PET technologies. The reader should consult other TriMark reports at http://www.trimarkpublications.com for a detailed discussion of the other important individual market segments that are related to the medical imaging markets, such as X-ray and radiography, mammography, magnetic resonance imaging (MRI), ultrasound, gamma camera market, computed tomography (CT) scans, and picture archiving and communication systems (PACS).

This report concentrates on the medical imaging market segment in important worldwide markets such as the U.S. and Europe. It focuses primarily on the hospital market segment, and, separately, on a description of the instruments, reagents and supplies marketed by major companies in the PET segment. The analysis discusses the market size, growth rates and market components for instruments and reagents, controls and consumables used in PET, with mention of contrast media and biopharmaceuticals used to enhance imaging

resolution. This study reviews the market for medical imaging in the clinical and research hospital market. It defines the dollar volume of sales of the market, both worldwide and in the U.S., and analyzes the factors that influence the size and the growth of the market segments.

The report discusses activity and trends in the PET market and goes on to discuss in detail the trends that have stimulated this market. This analysis also comments on the patterns of information processing in the PET market. It surveys all of the companies known to be marketing, manufacturing or developing PET equipment in the U.S. and worldwide. Leading companies are discussed in depth with a section on the history of the company, the product line, business and marketing analysis, and a subjective commentary of the position of the company in its market.

1.2 Methodology

The author of this report is a Ph.D. in biochemistry from the University of Minnesota with many decades of experience in science writing and as a medical industry analyst. He has been a senior director of several large regional and national healthcare laboratories. The editor is a retired college professor with three decades of experience in teaching biochemistry, biotechnology and pharmacology. Company-specific information is obtained mainly from industry trade publications, academic journals, news and research articles, press releases and corporate websites, as well as annual reports for publicly-held firms. Additionally, important data sources include American Hospital Association (AHA), American College of Radiology (ACR), World Health Organization (WHO), National Cancer Institute, American Cancer Society (ACS), International Atomic Energy Agency (IAEA), *Journal of Nuclear Medicine and Technology* (JNMT), *Biomedical Imaging and Intervention Journal*, International Academy of Cardiovascular Sciences and Medical Imaging & Technology Alliance (MITA). Where possible and practicable, the most recent data available have been used.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information in this study was obtained from sources that TriMark believes to be reliable, but do not guarantee the accuracy, adequacy or completeness of any information or omission or for the results obtained by the use of such information. Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals regarding commercial potential and market sizes.

Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects and Sector Snapshots that we publish annually. We extract relevant data and analytics from TriMark's research in the past three years as part of this data collection. We also extract qualified data feeds from e-questionnaire responses and primary research responses for this compilation.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government affiliated trade releases, and other published information as part of its secondary research materials. The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations. The report conclusions are verified through intensive interviewing of the top-ranking companies in the industry.

TriMark Publications Report Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report in TriMark Publications includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly-available data and proprietary databases.

- Formulating a study outline with the assigned writer, including important items, as follows:

    - Market and product segment grouping, and evaluating their relative significance.
    - Key competitors' evaluations, including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
    - End-user research to evaluate analytical significance in market estimation.
    - Supply chain research and analysis to identify any factors affecting the market.
    - New technology platforms and cutting-edge applications.

- Identifying the key technology and market trends that drive or affect these markets.

- Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.

- Completing a confirmatory primary research assessment of the report's findings with the assistance of expert panel partners.

1.3 Executive Summary

There will be a steady increase in demand for PET services as resolution improves and PET is combined with other modalities like CT. The medical imaging segments are poised for a major new phase of growth fueled by the availability of new technology coming out of the computer and digital information technology segment. Continuous improvements in technology are resulting in a growing number of new imaging tests that combine high levels of accuracy with rapid, easy-to-use product formats. Another major driver is the high interest of individual older baby boom patients and general healthcare consumers to monitor health status. Competition in the development and marketing of PET products is intense, and these diagnostic technologies have been subject to rapid change. We estimate that the competitive factors in the PET market include resolution, price and product performance as well as the distribution, advertising, promotion and brand-name recognition of the marketer. There are relatively few large, dominant global players selling PET equipment; these are matched by many small companies with a few or one product aiming at niche markets. A relative handful of firms led by GE Medical Systems, Philips Medical Systems International BV and Siemens Medical Solutions dominate the world medical imaging equipment market. However, due to the broad technology underlying the various forms of medical imaging, there are many other companies that perform very well in this sector, such as:

- Carestream Health, Inc. (U.S.).
- Fonar Corporation (U.S.).
- Hitachi Medical Systems America, Inc. (U.S.).
- Hologic, Inc. (U.S.).
- Medison America, Inc. (U.S.).
- The Esaote Group (Italy).
- TomTec Imaging Systems GmbH (Germany).
- Toshiba America Medical Systems (U.S.).

With the development of combined PET/CT devices, the market for PET scanners has decreased as it has increased for PET/CT scanners. The number of commercial facilities providing FDG has increased and the number of doses of FDG provided per facility has increased. PET/CT scanners continue to improve, and provide better quality images in shorter acquisition times. The PET/CT scanners have resulted in the capability of doing more patients per day than could be done by PET alone devices. Because of the reimbursement and the rapid expansion of clinical indications, the PET market grew rapidly. Most metropolitan areas in the U.S. have ready access to FDG and back-up production sites are generally available to provide FDG if a primary site has a problem.

PET became a [redacted] dollar industry as early as in [redacted]. The current new sales are [redacted]% PET/CT, with very few PET alone devices being sold. The reasons that PET only systems were being bought in recent years are the following: software image fusion can provide registration of the PET with CT or MRI images; CT adds from $[redacted] to $[redacted] to the cost of the device. The reasons that combined PET/CT devices are being bought are the following: noise-free attenuation correction; short duration transmission scans; shorter duration scans and faster patient throughput; anatomic lesion localization; potential added revenue from CT; competition factor (having the newest and best); adjunct to already established CT service (additional CT access); and improved registration, not only for diagnostic purposes but also for use with radiation oncology for radiation therapy planning and intensity-modulated radiation therapy.

The efficacy of dedicated PET and PET/CT scanners depends on the type of scintillation crystal employed in the detector and the crystal oxyorthosilicates was the clear winner in [redacted]. For Siemens, over half of its orders in 2010 were for scanners with the LSO (lutetium oxyorthosilicate) crystal. For Philips Medical Systems, its proprietary GSO (gadolinium oxyorthosilicate) offers improved throughput and image quality by allowing more counts than BGO (bismuth germanate) and sodium iodide, the older, established crystal technologies. Philips and Siemens provide PET scanners with BGO scintillators as lower cost recourse to their premium systems. Philips' Allegro and Siemens' Ecat Accel are built from fast scintillators, as the wave of the future. These manufacturers, along with CTI Molecular Imaging, see a chance to gain not only revenue but a marketing edge over rival GE Medical Systems. That edge is achievable for both dedicated PET and PET/CT scanners, because GE's PET systems use only BGO. The collaboration between CTI and Siemens, called CTI PET Systems (CPS) provides both companies with LSO-based detectors. CTI announced booming sales in [redacted], mostly due to the increasing popularity of LSO. Siemens' sales outperforms those of CTI mainly because of Siemens' name recognition and its well-established distribution channels in radiology. Speed is responsible for the growing popularity of LSO and GSO. These two crystals, after emitting a flash of light, become ready to emit another flash in about [redacted] nanoseconds. BGO needs a period five times as long. The time required for an imaging is thus much shorter for GSO- and LSO-based systems than those built around BGO.

The global market for PET/CT is on the upswing as PET's clinical use continues to attract global recognition. The hybrid PET/CT is increasing PET's functionality with radiologists, enabling the images easier to interpret in a familiar format. Growth in number of procedures is also increasing mainly due to approvals of indications such as breast imaging and increased utilization of PET in detecting lung cancer, colon cancer, lymphoma and melanoma. The major application of PET is only in oncology and yet, utility in cardiology applications is expanding in diagnosing myocardial viability and follow-up to equivocal SPECT studies. Procedure volume is also being propelled by the availability of PET/CT with multislice configurations appropriate for cardiac imaging. The quick adoption of PET/CT has increased the financial pressure on PET service providers and as a result they are trying to offset the high capital investment with billable procedures. This has generated unprecedented competition for PET referrals. PET/CT has been accepted very quickly both in the U.S. and internationally. Vendors have geared up for higher shipments in the U.S., anticipating sales growth. The cost of PET scanners has declined to an average price of $[redacted] to $[redacted] per scanner. TriMark's research reveals that the global sales of PET systems will increase from about $[redacted] in [redacted] to $[redacted] by [redacted]. According to the market projection by [redacted], the number of PET cameras globally will increase from a mere [redacted] in [redacted] to [redacted] in [redacted]. TriMark estimates that the U.S. market for PET systems was worth about $[redacted] in [redacted] and it is anticipated to reach $[redacted] in [redacted]. TriMark's research also reveals that, in the U.S. there were approximately [redacted] PET units and this number is likely to increase to [redacted] units in [redacted].