

TriMark Publications

May 2011
Volume: TMRNUCARD11-0501

NUCLEAR CARDIOLOGY MARKETS *(SAMPLE COPY, NOT FOR RESALE)*

Trends, Industry Participants, Product Overviews and Market Drivers

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1. Overview

An estimated [REDACTED] [REDACTED] ([REDACTED]%) of annual global deaths are due to various forms of cardiovascular disease (CVD). Of this huge mortality incidence, [REDACTED] are caused by ischemic heart disease and [REDACTED] deaths are due to hypertension and other cardiac conditions. A minimum of [REDACTED] people survive heart attacks and strokes every year, and a significant number of them undergo costly clinical and long-term care. As such, nuclear cardiology diagnostics has emerged as a leading non-invasive techniques to evaluate myocardial blood flow, assess the pumping function of the heart, as well as visualize the size and location of a heart attack. Among the different techniques of nuclear cardiology, myocardial perfusion imaging is the most frequently used.

Despite the enhanced image quality and increasing utilization rates of competing devices such as computed tomography (CT), magnetic resonance imaging (MRI) and diagnostic procedures such as CT angiography, single-photon emission computed tomography (SPECT) procedures performed with gamma cameras will continue to be used for a significant number of cardiac specific nuclear imaging procedures. The continued use of SPECT will be due to the lower purchase and maintenance costs, smaller physical footprint and easier service logistics of gamma cameras. In recent times, SPECT technologies are being combined with other imaging modalities, such as CT to design hybrid imaging modalities such as SPECT/CT. Hybrid imaging is preferred because it brings together the anatomical image benefits of CT and the functional information offered by SPECT into a single image, although hybrid systems are relatively more expensive than gamma cameras.

The nuclear cardiology market is heavily dependent upon the U.S. The region contributes the single largest share of the worldwide market, followed by Europe and Japan. China, India and Korea are also experiencing a high growth rate in nuclear medicine. The positron emission tomography (PET) scanners segment is likely to be the largest segment in the global nuclear medicine market. But, the gamma cameras segment is predicted to drive future growth. This TriMark Publications study discusses key products in nuclear cardiology and examines the trends that are stimulating this market. It includes a survey of all major companies actively engaged in marketing, manufacturing or developing nuclear cardiological instrumentation, with each company discussed in depth.

The main objectives of this analysis are to:

- Identify viable technology drivers through a comprehensive look at platform technologies for nuclear cardiology testing.
- Obtain a complete understanding of the individual nuclear cardiology testing platforms from their basic principles to their clinical applications.
- Discover feasible market opportunities by identifying high-growth applications in different clinical diagnostic areas.
- Focus on global industry developments through an in-depth analysis of the major world markets for nuclear cardiology technology, including growth forecasts.
- Present market figures related to the current value of nuclear cardiology, market projections, market share, key players, and sector growth rates.

An analysis of the nuclear cardiology market must include several key areas of related activity. The most important segments discussed in this report include:

- Hardware (*e.g.*, nuclear cardiology instrumentation).
- Software (*e.g.*, nuclear cardiology image processing, PACS).
- Radiopharmaceuticals and pharmaceuticals.
- Ancillary products.

This study aims at providing the reader with the following:

- An understanding of the most exciting nuclear cardiology market segments.
- Up-to-date information on the leading products, recent developments and R&D initiatives in the market.
- Knowledge of the nuclear cardiology market as an area of growth, research and investment.
- An extensive review of the nuclear cardiology hardware, software and radiopharmaceuticals markets, as well as the leading companies in these segments.
- A review of the market for clinical nuclear cardiology testing equipment and supplies used in the clinical hospital market.
- Dollar volume of the market sales, both worldwide and in the U.S., with an analysis of the factors that influence the size and growth of the market segments.
- Detailed analyses of new applications and trends in the nuclear cardiology marketplace.
- Views on the nuclear cardiology industry from leading industry experts.

Key questions answered in this examination are:

- How can nuclear cardiology tools and technologies facilitate improved patient care?
- What are the main types of nuclear cardiology technologies currently available?
- Who are the current key players in this marketplace?
- What is the current state of the nuclear cardiology market?
- What are the major trends in nuclear cardiology solutions?
- What is the impact of regulatory changes on nuclear cardiology markets?

1.2 Scope

This examination primarily focuses on three major segments of the nuclear cardiology market: 1) devices, 2) PACS (picture archiving and communications systems) and RIS (radiology information systems) and 3) radiopharmaceuticals. It discusses products, trends, new developments and compensation issues that are currently affecting or are likely to affect the market soon. Moreover, this report contains:

- Analysis of potential new nuclear cardiology testing applications in the clinical sector.
- Market predictions and trends analysis concerning U.S. expenditures on nuclear cardiology testing solutions.
- Projections of nuclear cardiology testing market sizes for European and Asian markets.
- Projections of future applications of non-invasive tests in nuclear cardiology testing-related screening.
- Analysis of commercial nuclear cardiology testing business strategies, such as co-branding.
- A comprehensive overview and insight into nuclear cardiology testing business strategies for growth in foreign markets.

The emphasis in this report is on those companies and products that are actively developing and marketing nuclear cardiology instrumentation. The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for a detailed discussion of the important individual market segments related to the nuclear cardiology market, such as cardiac rhythm management devices and medical imaging markets.

1.3 Methodology

The author of this report is an M.D. with many decades of experience in science writing and as a medical industry analyst. The editor is a retired college professor with three decades of experience in teaching biochemistry, biotechnology and pharmacology. He has four years of experience in writing healthcare reports. 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), American Society of Nuclear Cardiology (ASNC), European Council of Nuclear Cardiology, European Society of Cardiology (ESC), American College of Cardiology (ACC), American Heart Association (AHA), International Society for Heart Research (ISHR) 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.

1.4 Executive Summary

Nuclear imaging for cardiac diseases helps in accurately diagnosing the disease and blood flow blockages. Gamma cameras and PET scanners are the key imaging devices used for cardiac procedures. Though nuclear imaging in cardiology faces competition from other methods, the impact is relatively limited. Demand for diagnostic medical imaging equipment is mainly driven by the number of diagnostic procedures. The application of PET's clinical use, its combined use with other imaging equipment and the current shift to PET/CT imaging and SPECT/CT imaging are the important factors driving the dramatic rise in procedural volumes. Additionally, advancements in molecular imaging, evolution of image-guided interventions, as well as aging population continue to fuel growth in the broader medical diagnostics market. New gamma cameras that are available in the market are relatively much faster and provide better quality images than earlier models.

GE Healthcare has developed a new radiotracer called Iodine-123 (AndroView) and it can be used for imaging the sympathetic nervous system to help improve heart failure (HF) screenings. This product can provide a more accurate stratification of HF. Although PET imaging provides better image quality and faster scanning times than SPECT, it is not prevalently used in cardiac imaging, because PET is more expensive and the isotopes have relatively a fast decay rate. Yet, there has been a boost in PET sales in the recent years due to the periodic SPECT isotope shortages. PET procedures employ four or five different radiotracers and the most common and standard one used in cardiac imaging is rubidium 82 (CardioGen 82). The greatest drawback of rubidium is its cost and on an average a nuclear cardiology facility will have to spend about \$ [REDACTED] to \$ [REDACTED] per month.

Other reasons for the SPECT witnessing some decline in the recent years was due to some decline in the number of SPECT myocardial perfusion procedures as well as reduced pricing for Cardiolite and Myoview because of generic sestamibi. Future growth in SPECT is anticipated from specialized products for imaging myocardial infarction and neuronal imbalances in patients that require pacemakers or may be subject to congestive heart failure. Most of these products are in late stage development and will be launched in the near future.

TriMark estimates that the U.S. market for SPECT and PET radiopharmaceuticals was worth about \$ [REDACTED] and anticipates this to grow and reach \$ [REDACTED] in [REDACTED]. Total SPECT radiopharmaceutical sales were down [REDACTED]% in [REDACTED] primarily due to reductions in pricing of perfusion agents with the launching of generic sestamibi. SPECT procedure volume was also down due to the technetium shortage. The pressures are only temporary and eventually the market will become stable for SPECT radiopharmaceuticals. Revenue from PET radiopharmaceuticals was slightly down because of price weakness in the FDG market. However, future sales growth will be more in line with procedure growth. Of late, there has been some relief in the reimbursement for PET procedures, specifically in cardiology. Most vendors are investing in new PET agents in all segments, which indicate increased market once the new products are introduced. Sustained enhancements in imaging technology in both SPECT and PET are permitting higher resolution and shorter imaging times. Radiopharmaceutical doses are also getting minimized due to increased imaging efficiency.

SPECT imaging is an integral part of the standard work-up for almost all cardiac diseases. SPECT is being used to measure the state and extent of disease and are used frequently in most regions around the world. Myocardial Perfusion Imaging is regarded as the standard for symptomatic detection of coronary artery disease. Over [REDACTED] procedures are performed annually in the U.S. According to our estimates, the global market for SPECT scanner was worth about \$ [REDACTED] in [REDACTED] and is estimated to reach \$ [REDACTED] in [REDACTED]. Vendors of nuclear medicine equipment comprise: GE Healthcare, Philips Medical Systems Siemens Medical Solutions Ltd., Toshiba Medical Systems, Lantheus and Mallinckrodt Inc. GE Healthcare is the leader among these players in the SPECT market with its radiotracer Myoview (technetium Tc-99m tetrofosmin), which is quite efficient in the diagnosis and localization of regions of reversible myocardial ischemia in the presence or absence of infarction under both rest and stress. Myoview has a half-life of six hours and therefore it can be shipped as a unit dose as required via next-day delivery.