

Global ^{18}F -Sodium Fluoride PET Imaging Agent Market Growth 2026-2032

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Abstracts

The global ^{18}F -Sodium Fluoride PET Imaging Agent market size is predicted to grow from US\$ 26.76 million in 2025 to US\$ 48.33 million in 2032; it is expected to grow at a CAGR of 8.7% from 2026 to 2032.

^{18}F -Sodium Fluoride PET Imaging Agent is a fluorine-18-labeled diagnostic radiopharmaceutical primarily supplied as a sterile intravenous injection for PET or PET/CT bone imaging. Following administration, ^{18}F -fluoride is rapidly cleared from blood and is incorporated at sites of active bone mineralization, allowing visualization of altered osteogenic activity and bone remodeling. The market is centered on commercial ^{18}F -NaF finished radiopharmaceuticals produced through cyclotron-based fluorine-18 generation, automated radiochemical preparation, quality control, aseptic filling or dispensing, and time-sensitive distribution to PET imaging sites. Major product presentations include multi-dose vials and patient-specific unit doses, while production models include centralized commercial radiopharmacies, institutional on-site facilities, and hybrid networks. Clinical demand is concentrated in oncology bone imaging, including evaluation of suspected skeletal metastases, with additional use in selected non-oncology bone disorders. Because fluorine-18 has a physical half-life of approximately 110 minutes, production location, distribution radius, local PET infrastructure, and scheduling efficiency are integral characteristics of the commercial market rather than conventional pharmaceutical logistics.

Key Findings

In 2025, the average gross margin of the ^{18}F -sodium fluoride PET imaging agent industry is estimated at approximately 35%–45%. North America accounted for approximately 45.32% of global sales in 2025, maintaining its position as the largest

regional market. Europe represented approximately 21.20% of the global market, while India, Australia and New Zealand, Latin America, and Türkiye formed the second tier of regional demand. China remains at an early stage of commercial expansion from a relatively low base, with the approval of the country's first ^{18}F -sodium fluoride PET imaging agent in 2024 helping establish a formal commercial supply system. Oncology bone imaging remains the largest clinical application, with bone metastasis assessment representing the core source of demand. $^{99\text{m}}\text{Tc}$ -based bone imaging agents and disease-specific PET tracers continue to create substitution pressure, positioning ^{18}F -NaF as a specialized PET bone imaging tool rather than a universal replacement.

Market Trends

The market is moving from isolated institutional production toward more structured regional radiopharmacy networks. Short isotope half-life makes decentralized or hub-and-spoke production economically important, encouraging manufacturers to expand cyclotron coverage, radiochemistry capacity and last-mile delivery rather than rely on a small number of national manufacturing plants.

Product differentiation is increasingly based on manufacturing reliability, calibrated-dose accuracy, scheduling flexibility and distribution reach rather than molecular innovation. Multi-dose production remains efficient for high-throughput centers, while patient-specific unit-dose supply supports smaller PET facilities and geographically distributed customers.

A second trend is the widening geographic commercialization of ^{18}F -NaF. Mature PET markets already possess the technical infrastructure required for production, while China and several emerging markets are progressively converting research and hospital-preparation capability into formally approved commercial radiopharmaceutical supply.

Market Dynamics

Drivers

Expansion of PET and PET/CT infrastructure remains the fundamental demand driver. Greater availability of medical cyclotrons, automated synthesis systems and GMP-compliant radiopharmacies lowers the operational barrier to supplying a short-lived tracer such as ^{18}F -NaF. Oncology remains the principal demand foundation because skeletal metastasis assessment continues to represent a clinically important imaging

requirement, particularly in cancers with a high propensity for bone involvement.

Improved commercial availability is also supporting demand. The entry of additional approved products and regional production nodes reduces transportation constraints and enables more hospitals and imaging centers to schedule ^{18}F -NaF examinations within the isotope's limited usable window.

Restraints

Reimbursement is one of the most significant constraints. In the United States, current CMS national policy continues to state that there are no nationally covered indications for NaF- ^{18}F PET under NCD 220.6.19, limiting broad Medicare-driven adoption despite extensive PET infrastructure.

^{18}F -NaF also competes with established $^{99\text{m}}\text{Tc}$ -MDP/HDP bone scintigraphy, which benefits from extensive installed infrastructure and established clinical workflows. In selected cancer indications, disease-specific PET radiopharmaceuticals can provide information beyond skeletal osteogenic activity, creating additional substitution pressure.

Opportunities

China represents one of the clearest incremental opportunities because its commercial market is starting from a low base while PET imaging capacity and domestic radiopharmaceutical manufacturing continue to expand. Formal product approvals can shift a portion of demand from research preparation and local institutional synthesis toward standardized commercial supply.

Regional production networks also create opportunities in markets where PET infrastructure exists but reliable ^{18}F -NaF delivery remains limited. Manufacturers capable of linking cyclotron capacity, automated production, quality control and rapid distribution can expand addressable territory without relying solely on higher pricing.

Challenges

The approximately 110-minute half-life of fluorine-18 creates a structurally difficult supply chain. Manufacturing delays, quality-control failures, transport disruption or patient rescheduling can directly result in unusable doses and revenue loss. Utilization rates therefore depend heavily on production planning and route density.

Another challenge is demonstrating a sufficiently differentiated clinical and economic value proposition. High imaging sensitivity alone does not guarantee reimbursement or routine adoption when alternative bone imaging techniques are cheaper or already embedded in treatment pathways.

Industry Chain Analysis

The upstream industry includes enriched oxygen-18 water, medical cyclotrons, targets, automated radiochemical synthesis modules, hot cells, sterile dispensing equipment, radiation shielding, quality-control instruments and specialized consumables. Fluorine-18 is generally generated through cyclotron irradiation and subsequently formulated as sodium fluoride F-18 under controlled radiopharmaceutical production conditions.

Midstream participants include commercial PET radiopharmacies, regional cyclotron operators and qualified hospital or academic production facilities. Their key capabilities include radionuclide production, radiochemical preparation, sterility and quality control, calibrated dispensing and rapid logistics. Downstream demand is generated primarily by hospitals, independent diagnostic imaging centers and academic or research institutions equipped with PET or PET/CT systems.

Value Chain Analysis

Value creation is concentrated less in the chemical complexity of sodium fluoride itself and more in the ability to produce, release and deliver a compliant radioactive dose within a very short time window. Cyclotron utilization, batch scheduling, quality-control turnaround, dose utilization and delivery density therefore have a direct impact on unit economics.

Large commercial radiopharmacy networks benefit from shared cyclotron infrastructure and route density, while local institutional production can eliminate part of the delivery requirement but often operates at smaller scale. The strongest commercial positions are generally associated with manufacturers that combine production capacity, regulatory compliance, regional customer density and reliable delivery.

Segment Insights

By Clinical Application, Oncology Bone Imaging remains the dominant segment, supported by evaluation of suspected skeletal metastases and altered osteogenic

activity in cancer patients. Non-oncology Bone Imaging represents a smaller segment covering selected metabolic, inflammatory, traumatic and other bone disorders, while other clinical uses remain comparatively limited.

By Production and Supply Model, Centralized Commercial Radiopharmacy Production is the most important commercial segment because it generates identifiable external product revenue and supports multiple PET centers. Hospital or Institutional On-site Production remains relevant to total procedure volume but contributes less directly to the commercial finished-product market, while Hybrid Production and Supply models combine institutional use with external distribution.

By Dose Presentation, Multi-dose Vials provide production efficiency in higher-throughput settings, whereas Patient-specific Unit Doses are important for decentralized imaging centers and scheduled deliveries. The preferred presentation depends on local demand density, production timing and radiopharmacy workflow.

Downstream Market Opportunities

Hospitals and dedicated diagnostic imaging centers represent the principal commercial opportunity. Growth potential is strongest where PET/CT utilization is increasing but specialized radiopharmaceutical production remains locally constrained, because reliable regional supply can directly unlock additional clinical use.

Oncology-focused imaging networks offer particularly attractive demand characteristics due to recurring requirements for staging, treatment planning and reassessment. However, the opportunity is indication-specific, and suppliers must account for competition from other PET tracers and conventional skeletal imaging.

Regional Insights

North America retains the largest commercial demand base and the deepest concentration of qualified PET radiopharmacy production. The region benefits from extensive cyclotron and PET infrastructure, but reimbursement constraints limit the conversion of technical capacity into routine NaF-18 procedure growth. CMS policy therefore remains an important structural factor in the regional outlook.

Europe represents the second-largest regional demand base, supported by established nuclear medicine infrastructure but characterized by fragmented country-level reimbursement and radiopharmacy networks. India has developed a notable regional

manufacturing base, while Australia and New Zealand benefit from established commercial PET radiopharmacy supply. China is the most important low-base expansion market in the report's regional framework, supported by recent domestic product commercialization.

Competitive Landscape Analysis

The competitive landscape is highly regional because a short product half-life limits practical distribution radius. North America has the broadest commercial production network and the highest concentration of regional radiopharmacies, while Europe is more fragmented across national and sub-national supply systems. China is substantially more concentrated, reflecting the comparatively recent transition toward formally approved commercial ^{18}F -NaF products.

Competition is therefore determined primarily by production-node coverage, cyclotron reliability, customer proximity, regulatory capability and delivery performance rather than by conventional pharmaceutical branding. Mature regions favor multi-site radiopharmacy networks, while emerging regions provide room for new approved manufacturers and regional production centers as PET infrastructure expands.

Report Scope

LP Information, Inc. (LPI) ' newest research report, the “ ^{18}F -Sodium Fluoride PET Imaging Agent Industry Forecast” looks at past sales and reviews total world ^{18}F -Sodium Fluoride PET Imaging Agent sales in 2025, providing a comprehensive analysis by region and market sector of projected ^{18}F -Sodium Fluoride PET Imaging Agent sales for 2026 through 2032. With ^{18}F -Sodium Fluoride PET Imaging Agent sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US\$ millions of the world ^{18}F -Sodium Fluoride PET Imaging Agent industry.

This Insight Report provides a comprehensive analysis of the global ^{18}F -Sodium Fluoride PET Imaging Agent landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyzes the strategies of leading global companies with a focus on ^{18}F -Sodium Fluoride PET Imaging Agent portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms' unique position in an accelerating global ^{18}F -Sodium Fluoride PET Imaging Agent market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for 18F-Sodium Fluoride PET Imaging Agent and breaks down the forecast by Dose Presentation, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global 18F-Sodium Fluoride PET Imaging Agent.

This report presents a comprehensive overview, market shares, and growth opportunities of 18F-Sodium Fluoride PET Imaging Agent market by product type, application, key manufacturers and key regions and countries.

Market Segmentation

Segmentation by Dose Presentation:

Multi-dose Vial

Patient-specific Unit Dose

Others

Segmentation by Production and Supply Model:

Centralized Commercial Radiopharmacy Production

Hospital or Institutional On-site Production

Hybrid Production and Supply

Others

Segmentation by Application:

Oncology Bone Imaging

Non-oncology Bone Imaging

Others

This report also splits the market by region:

Americas

United States

Canada

Mexico

Brazil

APAC

China

Japan

Korea

Southeast Asia

India

Australia

Europe

Germany

France

UK

Italy

Russia

Middle East & Africa

Egypt

South Africa

Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analysing the company's coverage, product portfolio, its market penetration.

Siemens Healthineers AG

Cardinal Health, Inc.

SOFIE Co.

BAMF Health Inc.

Precision Nuclear LLC

SPECTRON mrc, LLC

CMPM Pharmacy Services Holding LLC

Voxel S.A.

BIOKOSMOS

SintiAS Group of Companies

Cyclotek (Aust) Pty Ltd

Shreeji Imaging and Diagnostic Centre Private Limited

PositronPharma S.A.

Atom High Tech Co., Ltd.

Yantai Dongcheng Pharmaceutical Group Co., Ltd.

Board of Radiation & Isotope Technology

Key Questions Addressed in this Report

What is the 10-year outlook for the global 18F-Sodium Fluoride PET Imaging Agent market?

What factors are driving 18F-Sodium Fluoride PET Imaging Agent market growth, globally and by region?

Which technologies are poised for the fastest growth by market and region?

How do 18F-Sodium Fluoride PET Imaging Agent market opportunities vary by end market size?

How does 18F-Sodium Fluoride PET Imaging Agent break out by Dose Presentation, by Application?

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