

# **Radiopharmaceutical Theranostics Market Forecast to 2028 - COVID-19 Impact and Global Analysis By Product Type [Alpha Emitters, Beta Emitters, and Positron Emission Tomography (PET) Tracers], Radioisotope [Technetium-99, Gallium-68, Iodine-131, Iodine-123, 18F, Y-90, Lutetium (Lu) 177, Copper (Cu) 67, Copper (Cu) 64, and Others], Source (Nuclear Reactors and Cyclotrons), Application [Targeted Therapeutic (Rx) and Companion Diagnostic (DX)], Indication (Oncology, Cardiology, Neurology, and Others), and End User (Hospitals, Diagnostic Imaging Centers, Academic and Research Institutes, and Others)**

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## **Abstracts**

The radiopharmaceutical theranostics market is expected to reach US\$ 3,441.97 million by 2028 from US\$ 1,814.58 million in 2022; it is estimated to grow at a CAGR of 11.3% from 2022 to 2028. The rising incidence of cancer and rising application in treatment of cardiovascular disorder are among the key forces bolstering the market. However, regulatory challenges for the approval of radiopharmaceutical theranostics hinder the radiopharmaceutical theranostics market growth.

Radiopharmaceuticals are important in the diagnosis and therapy of cancer; a diagnostic scan with <sup>123</sup>I, <sup>124</sup>I, or low-activity <sup>131</sup>I-iodide is followed by therapy with high-activity <sup>131</sup>I-iodide. Similarly, adrenergic tumors such as pheochromocytoma and

neuroblastoma can be imaged with  $^{123}\text{I}$ -meta-iodobenzylguanidine and treated with  $^{131}\text{I}$ -metaiodobenzylguanidine. Bone scintigraphy can be used to select patients with painful bone metastases that progressed from prostate cancer. They might benefit from treatment with beta- or alpha-particle-emitting bone-seeking agents, the newest and most successful of which is  $^{223}\text{Ra}$  radium chloride. Somatostatin receptor targeting peptides for diagnosing and treating neuroendocrine tumors with agents such as  $^{68}\text{Ga}$ -DOTATATE and  $^{177}\text{Lu}$ -DOTATATE, respectively, are among the recently established theranostics.

Cancer is one of the leading causes of death worldwide, responsible for almost 10 million deaths in 2020, or almost one in six. The most common types of cancer are breast, lung, colon, rectum, and prostate. According to National Cancer Registry Program Report 2020, in India, male cancer cases were estimated at 679,421 in 2020 and are expected to further increase to about 763,575 in 2025, while female cancer cases were estimated at 712,758 in 2020 and 806,218 in 2025. As people age, they become immunocompromised and often succumb to cancer risks. Poor lifestyles, longer working hours, increasingly stressful lives, smoking, alcohol consumption, contraceptive use, nulliparity, and reduced breastfeeding all contribute to breast cancer incidence.

According to the American Cancer Society's 2023 report, ~43,720 new cases of thyroid cancer (12,540 in men and 31,180 in women) are recorded in 2023. The report also revealed that 2,120 deaths occurred from thyroid cancer (970 in men and 1,150 in women) in the same year. Radiopharmaceutical theranostics have promising potential in cancer therapy. Theranostics is the combination of therapeutic and diagnostic techniques that utilize a suitable radiopharmaceutical agent. For example, radioiodine has a well-known theranostic application in diagnosing and treating differentiated thyroid cancer. Several radiopharmaceutical theranostic pairs are available for breast cancer applications. These pairs include  $^{43}/^{44}\text{Sc}/^{47}\text{Sc}$ ,  $^{64}\text{Cu}/^{67}\text{Cu}$ ,  $^{83}\text{Sr}/^{89}\text{Sr}$ ,  $^{86}\text{Y}/^{90}\text{Y}$ ,  $^{110}\text{In}/^{111}\text{In}$ ,  $^{124}\text{I}/^{131}\text{I}$ ,  $^{152}\text{Tb}/^{161}\text{Tb}$ ,  $^{152}\text{Tb}/^{149}\text{Tb}$ ,  $^{68}\text{Ga}/^{177}\text{Lu}$ , and  $^{90}\text{Y}/^{177}\text{Lu}$ .  $^{123}\text{I}/^{131}\text{I}$  is a well-known example of theranostic pair that is used in high-quality single-photon emission computerized tomography (SPECT)/CT for pre- and post-therapeutic assessment of thyroid cancer.

Malignant gliomas are deadly tumors with the availability of only a few therapeutic options.  $^{89}\text{Zr}$ - and  $^{177}\text{Lu}$ -labeled Lumi804- $\alpha$ CD11b is a promising theranostic technique intended for monitoring and reducing tumor-associated myeloid cells (TAMCs) in gliomas and improving immunotherapy outcomes. Further, theranostics are incorporated in radiometals for PET imaging and targeted radiopharmaceutical therapy (TRT). DOTA-octreotate (dotatate) radiolabeled with Lu-177 ( $^{177}\text{Lu}$ -dotatate: Lutathera)

or Ga-68 (68Ga-dotatate: NetSpot) are approved by the Food and Drug Administration (FDA) for targeted radiopharmaceutical therapy (TRT) and positron emission tomography (PET) imaging. Thus, a radiopharmaceutical theranostic approach has unprecedented value in diagnosing and treating different types of cancer, which fuels the overall radiopharmaceutical theranostics market growth.

### Product Type Insights

Based on product type, the radiopharmaceutical theranostics market is segmented positron emission tomography (PET) tracers, beta emitters, and alpha emitters. In 2022, the positron emission tomography (PET) tracers segment held the largest market share in radiopharmaceutical theranostics market, and it is anticipated to register the highest CAGR during the forecast period (2022–2028). PET is an imaging technique that provides quantitative information on the distribution of PET radiopharmaceuticals in the body. PET imaging requires expensive equipment, which includes a cyclotron for radionuclide production, automated chemistry devices, purification instrumentation, and PET cameras. PET imaging is used in areas such as cardiology, neurology, and cancer diagnosis. PET may detect the early onset of disease before it is evident on other imaging tests. Better resolution can be achieved via PET using positron emitters, such as gallium-68 and fluorine-18. PET tracers featuring radioactive copper have also been developed as a promising alternative for existing hypoxia imaging techniques due to their high membrane permeability and low redox potential. The success of Ga-PSMA-11 further inspired the development of PSMA-targeting PET tracers for imaging prostate cancer. Additionally, theranostics PET tracers are progressively used in radiopharmaceutical drug development and its application. Theranostic PET tracers have the potential to serve as a noninvasive whole-body navigator, which helps select the most effective drug candidates, and determine optimal dosage and administration route. Thus, benefits such as higher resolution, and quantification of activity boost the radiopharmaceutical theranostics market for the PET tracers segment.

### Radioisotope Insights

Based on radioisotope, the radiopharmaceutical theranostics market is segmented Lutetium (Lu) 177, Gallium-68, Iodine-131, Iodine-123, Technetium-99, Yttrium-90 (Y-90), Copper (Cu) 64, 18F, Copper (Cu) 67, and others. In 2022, the Lutetium (Lu) 177 segment held the largest market share in radiopharmaceutical theranostics market, and it is anticipated to register the highest CAGR of 12.3% during the forecast period (2022–2028). Lutetium-177 (177Lu) is the latest addition to the field of nuclear medicine. It has potential to become one of the most extensively used therapeutic

radionuclides in the coming years. Lu-177 PSMA therapy for cancer theranostic is employed to treat advanced prostate cancer cases. Lu-177 octreotate therapy is used to treat neuroendocrine tumors (NETs), including head and neck cancers and gastrointestinal tumors. Lutetium therapy (lutetium-177-DOTA-oxodotretotide) has been identified as targeted radionuclide therapy or peptide receptor radionuclide therapy (PRRT). The US Food and Drug Administration (FDA) has approved 177Lu-labeled DOTA-TATE for peptide receptor radionuclide therapy (PRRT).

### Source Insights

Based on source, the radiopharmaceutical theranostics market is divided into cyclotrons and nuclear reactors. In 2022, the cyclotrons segment held a larger market share in radiopharmaceutical theranostics market and is anticipated to register a higher CAGR during the forecast period (2022–2028). Cyclotrons are best suited for producing proton-rich radioisotopes such as Fluorine-18 (18F). Commercially available cyclotron-produced medical radioisotope involves Carbon-11, Nitrogen-13, Oxygen-15, Fluorine-18 (18F), Copper-64, Gallium-67, Iodine-123, and Thallium-201. According to the International Atomic Energy Agency (IAEA) 2023 report, the most frequent radioisotope produced through cyclotrons are those with short half-lives, particularly fluorine-18, carbon-11, oxygen-15, and nitrogen-13, intended for imaging techniques such as positron emission tomography (PET). Cyclotrons account for almost 95% of the production of radiopharmaceuticals used in PET. Additionally, the demand for cyclotrons is increasing as radionuclides are majorly used in research, diagnosis, and treatment of a range of life-threatening diseases such as cancer, Parkinson's, Alzheimer's, and insomnia. Further, medical imaging techniques such as PET and SPECT depend on cyclotron-produced radioisotopes.

### Application Insights

Based on application, the radiopharmaceutical theranostics market is bifurcated into targeted therapeutic (Rx) and companion diagnostic (CDx). The targeted therapeutic (Rx) segment held a larger market share in radiopharmaceutical theranostics market in 2022, and it is expected to register a higher CAGR during the forecast period. Targeted therapeutics have emerged as a promising strategy for treating harmful clinical conditions, such as cancer. For example, 'radionuclide,' a type of radiation therapy, uses a cell-targeting molecule such as a monoclonal antibody injected into the body. Further, the cell-targeting molecule binds to a specific target molecule on cancer cells, subsequently killing the targeted cancer cells; the mechanism ensures minimum harm to normal cells. Targeted therapeutics are used for treating prostate cancer and other

types of cancers. This is well understood by the following case of targeting somatostatin receptors in neuroendocrine pancreatic tumors.

<sup>68</sup>Ga has been developed for somatostatin receptor imaging such as DOTATOC, DOTATATE, and DOTANOC. A somatostatin-receptor targeted therapy can be utilized for neoadjuvant therapy that renders inoperable pNET resectable by utilizing <sup>177</sup>Lu-DOTATATE (27) and <sup>90</sup>Y-DOTATATE (28). <sup>90</sup>Y is a beta-emitting radionuclide best suited for bulky pancreatic tumors. Additionally, <sup>177</sup>Lu-DOTATOC and <sup>213</sup>Bi-DOTATOC have revealed relatively high biological effectiveness, and they are effectively responsible for decreasing the survival of pancreatic adenocarcinoma cells.

### Indication Insights

Based on indication, the radiopharmaceutical theranostics market is segmented oncology, neurology, cardiology, and others. The oncology segment held the largest market share in radiopharmaceutical theranostics market in 2022, and it is anticipated to register the highest CAGR during the forecast period (2022–2028). Theranostics methods involve administering nanoparticles into the patient's body and using photodynamic therapy, which paves the way for personalized medicine. These methods can be applied in the treatment of esophageal cancer, prostate cancer, and breast cancer, in the treatment of actinic keratosis, actinic cheilitis, Bowen's disease, basal cell epithelioma, and macular degeneration. Therapeutic radiopharmaceuticals for cancer treatment are predominantly labeled with beta-emitting radionuclides. The radionuclides I-131, Lu-177, and Yttrium-90 (Y-90) are frequently used for this purpose. Upon decay, the emitted beta-particles travel 1–12 mm through tissue while losing energy and causing cytotoxic damage to the cell to induce apoptosis. Alternatively, and more recently, alpha-emitting radionuclides, e.g., At-211 or Ac-225, have been explored for therapeutic applications. Theranostics has been successfully used by clinicians and patients in treating prostate cancer. Thus, the strong clinical need for these therapies and targeted treatments in oncology continue to fuel the market for the oncology segment during the forecast period.

### End User Insights

Based on end user, the radiopharmaceutical theranostics market is segmented hospitals, diagnostic imaging centers, academic and research institutes, and others. The hospitals segment held the largest market share in 2022 of global radiopharmaceutical theranostics market. However, academic and research institutes

segment is anticipated to register the highest CAGR during the forecast period (2022–2028). Hospitals employ technologically advanced systems to treat cardiac aneurysms, neurology aneurysms, oncology tumors, and other similar conditions. The rising prevalence of various diseases and an increasing number of hospitals contribute to the growth of the radiopharmaceutical theranostics market for hospitals segment.



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