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# North America Radiopharmaceutical Theranostics Market Forecast to 2028 - COVID-19 Impact and Regional Analysis By Product Type [Alpha Emitters, Beta Emitters, and Positron Emission Tomography (PET) Tracers], Radioisotope [Technetium-99, Gallium-68, Iodine-131, Iodine-123, Yttrium-90 (Y-90), Fluorine-18 (18F), Lutetium (Lu) 177, Copper (Cu) 67, Copper (Cu) 64, and Others], Source (Nuclear Reactors and Cyclotrons), Application [Targeted Therapeutic (Rx) and Companion Diagnostic (CDx)], 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 North America radiopharmaceutical theranostics market is expected to reach US$ 1,529.88 million by 2028 from US$ 795.88 million in 2022; it is estimated to grow at a CAGR of 11.5% from 2022 to 2028.

The increasing incidences of chronic diseases, presence of supportive government plans, growing strategic initiatives by market players, and development of innovative radiotherapies are among the key forces bolstering the market. However, regulatory challenges for the approval of radiopharmaceutical theranostics hinder the North

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America radiopharmaceutical theranostics market growth.

Radiopharmaceuticals are important in the diagnosis and therapy of cancer; a diagnostic scan with 123I, 124I, or low-activity 131I-iodide is followed by therapy with high-activity 131I-iodide. Similarly, adrenergic tumors such as pheochromocytoma and neuroblastoma can be imaged with 123 I-meta-iodobenzylguanidine and treated with 131 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 223Ra radium chloride. Somatostatin receptor targeting peptides for diagnosing and treating neuroendocrine tumors with agents such as 68Ga-DOTATATE and 177Lu-DOTATATE, respectively, are among the recently established theranostics.

Atherosclerosis remains a dominant cause of cardiovascular diseases (CVDs). It acts as a life-threatening CVD resulting in chronic inflammation and abnormal lipid proliferation, and it is often difficult to treat on time due to the lack of noticeable symptoms in the initial phases. Due to their associated complexity and pathophysiology, CVDs have been presenting major challenges to healthcare systems in North American countries. Per the 2022 report by the Centers for Disease Control and Prevention (CDC), heart disease is a leading cause of death among men and women in the US. It was a cause of ~697,000 deaths, i.e., 1 in 5 deaths, in the US in 2020. A National Institute of Health (NIH) report states that theranostic nanoparticles have gained significant attention in the medical field, as the techniques help overcome complexities and pathophysiological complications associated with CVDs. Cardiovascular imaging of atherosclerosis patients provides pathophysiological evidence that can be used to treat these diseases. Further, theranostic nanoparticles can be combined with a range of imaging techniques, such as magnetic resonance imaging (MRI), positron emission tomography (PET), and computed tomography (CT). Various clinical research studies have been conducted in clinical laboratories so far. A three-in-one therapeutic complex has been constructed by combining a polymeric photoacoustic probe with nanoparticles-PLCDP@PMH. Clinical in-vivo evaluations reveal that the PLCDP@PMH supports the theranostics approach by enabling early-stage atherosclerosis detection in patients.

Radiopharmaceutical therapies (RPTs) involve injecting a particular radioactive drug (such as 200mCi for Lu-177-PSMA and Lu-177-DOTATATE) into patients undergoing therapy. However, upon injection, the doses delivered to organs and absorbed quantities of drugs show notable variations. Radiopharmaceutical therapies for tumors and normal tissues depend on absorbed doses; however, variations in absorption are

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difficult to control. A fixed administered dosage results in the undertreatment of patients, possibly leading to cases of dose toxicity. Theranostic digital twins (TDTs) can be employed in the drug development process to overcome such limitations. The TDTs investigate optimal injected radioactive drugs among patients at the sites of injection, along with determining injection intervals and profiles, and suitable combinational radiopharmaceutical therapies. Additionally, TDTs coupled with appropriate computational tools can be used in predictive absorbed radiation dose modeling. Further, TDTs promise zero uncertainties in the clinical results generated, thus acting as a powerful tool for offering truly personalized treatments to patients. Thus, the use of TDTs in personalized radiopharmaceutical therapies provides lucrative opportunities for radiopharmaceutical theranostics market players.

Product Type Insights

Based on product type, the North America 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 North America 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 North America radiopharmaceutical theranostics market for the PET tracers segment.

Radioisotope Insights

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Based on radioisotope, the North America 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 North America radiopharmaceutical theranostics market, and it is anticipated to register the highest CAGR of 12.7% 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-oxodotreotide) 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 North America radiopharmaceutical theranostics market is divided into cyclotrons and nuclear reactors. In 2022, the cyclotrons segment held a larger market share in North America 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 North America radiopharmaceutical theranostics market is

bifurcated into targeted therapeutic (Rx) and companion diagnostic (CDx). The targeted therapeutic (Rx) segment held a larger market share in North America 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.

68Ga 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 177Lu-DOTATATE (27) and 90Y-DOTATATE (28). 90Y is a beta-emitting radionuclide best suited for bulky pancreatic tumors. Additionally, 177Lu-DOTATOC and 213Bi-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 North America radiopharmaceutical theranostics market is segmented oncology, neurology, cardiology, and others. The oncology segment held the largest market share 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

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oncology continue to fuel the market for the oncology segment during the forecast period.

End User Insights

Based on end user, the North America 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. 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 market for hospitals segment.

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## 13. NORTH AMERICA RADIOPHARMACEUTICAL THERANOSTICS MARKET

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