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Theranostics in Oncology: Integrating Molecular Imaging and Targeted Radionuclide Therapy for Precision Cancer Care

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ABSTRACT

Background: Theranostics has become a key pillar of precision oncology, combining molecular imaging and targeted radionuclide therapy for individualized cancer diagnosis, treatment selection and response assessment. Theranostics, however, utilizes tumor-specific molecular targets to guide tailored patient care as opposed to conventional techniques that are focused primarily on morphological or histological classification. Its role in neuroendocrine tumors, prostate cancer and differentiated thyroid carcinoma has been demonstrated in clinical studies and is being explored in an increasing number of solid and hematologic malignancies.

Objective: This state-of-the-art overview covers the biological bases, clinical applications and emerging evidence of theranostics in modern oncology.

Methods: It provides a critical evaluation of major advancements in radiopharmaceutical research, quantitative molecular imaging, tailored dosimetry and artificial intelligence and discusses their potential for treatment optimisation as well as the limits that still prevent their broad use. We reviewed emerging molecular targets such as fibroblast activation protein (FAP), human epidermal growth factor receptor 2 (HER2), C-X-C chemokine receptor type 4 (CXCR4), gastrin-releasing peptide receptor (GRPR) and delta-like ligand 3 (DLL3), together with advances in alpha-particle therapy, ligand engineering and next-generation radiopharmaceuticals. Moreover, we discuss unmet obstacles such as the varied clinical evidence, the legal and infrastructural barriers, the availability of isotopes, cost-effectiveness, and the requirement of standardization of dosimetry and multidisciplinary integration.

Results: Theranostics has already changed the way some malignancies are treated, but for it to be used more widely in clinics there will need to be good quality data comparing different treatments, more access to radionuclides globally and new technology will need to be incorporated into everyday practice. Future progress is likely to include alpha-particle therapy, AI-guided tailored dosimetry, FAP-targeted theranostics, radiogenomics, combination radionuclide–immunotherapy approaches, and expanded radionuclide production. This study critically evaluates the current data and future approaches and highlights theranostics as an emerging platform that may revolutionize customized cancer therapy.

Keywords: *Theranostics; Precision oncology; Nuclear medicine; Radiopharmaceutical therapy; Molecular imaging; Targeted radionuclide therapy; Prostate-specific membrane antigen (PSMA); Peptide receptor radionuclide therapy (PRRT); Lutetium-177; Alpha-particle therapy; Personalized dosimetry; Artificial intelligence; Precision medicine.*

INTRODUCTION

Cancer is a prominent cause of morbidity and mortality worldwide, contributing to about 1 in 6 deaths globally and posing a large clinical, societal and economic burden. Despite advances in molecular biology, targeted therapies, immuno-oncology and precision medicine, treatment outcome is very diverse due to significant inter- and intratumoral heterogeneity. Standard imaging modalities such as computed tomography (CT) and magnetic resonance imaging (MRI) mainly provide anatomical information and often do not correspond to the molecular characteristics that drive tumor biology and treatment response. The same may be said for standardized systemic treatment procedures which may not sufficiently address the biological tumor heterogeneity, underlining the necessity for approaches integrating molecular diagnosis with customized therapy.

Theranostics, the combination of molecular imaging with targeted radionuclide therapy of the same biological target, has become an important breakthrough in precision oncology. This integrated method allows patient selection, treatment planning and response assessment in one molecular framework and connects diagnostic findings directly with therapeutic decision making. Thus, nuclear medicine has transformed from a largely diagnostic field to an important therapeutic specialty with an increasing role in personalized cancer management .

An example of this is radioactive iodine in differentiated thyroid cancer, one of the first successful examples of precision medicine. The last two decades have witnessed an enormous expansion of theranostics applications driven by breakthroughs in radiochemistry, molecular biology, hybrid imaging (PET/CT, PET/MRI and SPECT/CT) and radionuclide manufacture. These advances have permitted the highly sensitive imaging of tumor-specific targets and the invention of radiopharmaceuticals that can selectively transport therapeutic radionuclides to malignant tissue, laying the technological groundwork for current oncologic theranostics.

The best clinical data to date are from neuroendocrine tumors and metastatic prostate carcinoma. ^177Lu-DOTATATE peptide receptor radionuclide therapy (PRRT) has been established as a standard treatment for somatostatin receptor-positive neuroendocrine tumors by the NETTER-1 trial, and ^177Lu-PSMA radioligand therapy has shown significant survival and disease-control benefits in metastatic castration-resistant prostate cancer in the VISION and TheraP trials. The investigations have clearly established theranostics as an evidence-based therapeutic paradigm and not as an experimental technique. However, therapeutic effectiveness has been confined to a few cancers and evidence for wider use is mostly from early phase research. Whether the optimistic outcomes in new indications translate into comparable survival improvements is a question that requires confirmation in suitably powered randomized trials.

The therapeutic landscape is rapidly changing with the exploration of novel molecular targets such as fibroblast activation protein (FAP), human epidermal growth factor receptor 2 (HER2), C-X-C chemokine receptor type 4 (CXCR4), gastrin-releasing peptide receptor (GRPR), and integrins in a variety of solid and hematologic malignancies. Parallel improvements in alpha particle emitters, in particular ^{225}Ac and ^{212}Pb, offer the promise of enhanced cytotoxicity from high-linear-energy-transfer radiation, and may help to overcome resistance to conventional beta-emitting therapies. But many of these techniques are still exploratory, and significant questions about long-term safety, optimal patient selection, dosimetry and comparative effectiveness still need to be answered.

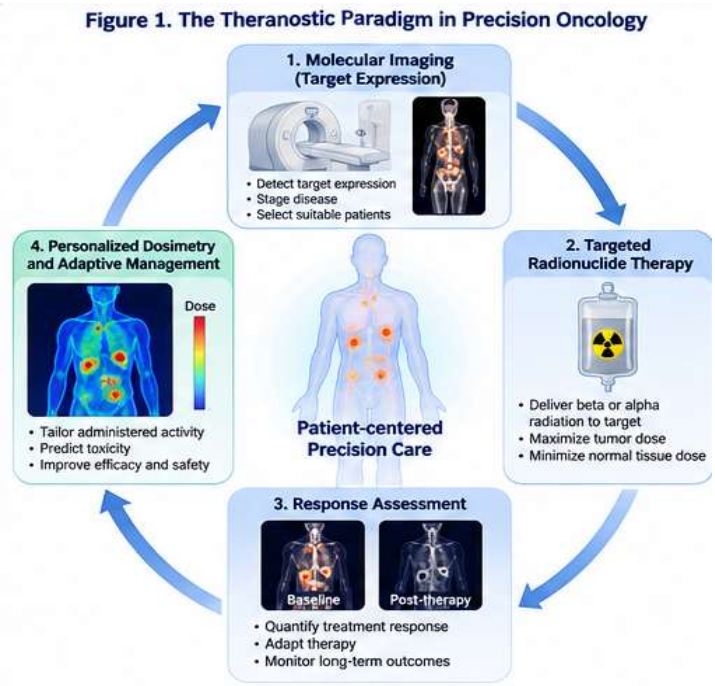
Technological innovation is also transforming the practice of theranostics. Artificial intelligence, radiomics, quantitative imaging and machine learning are increasingly employed in lesion detection, image reconstruction, tumor segmentation, response prediction and treatment planning. Similarly, personalized dosimetry has developed as an important component of radionuclide therapy, allowing patient-specific adjustment of given activity to maximize tumor irradiation while minimizing damage. While these improvements may allow for increased treatment precision, the limited

standardization, varying validation across institutions, and the lack of widely approved clinical workflows impede their routine use.

The advancement has been impressive yet there are still important impediments to the mainstream use of theranostics. Access is restricted in many healthcare systems because to limited radionuclide manufacturing capacity, complex supply chains, regulatory variability, reimbursement issues, infrastructural needs and shortages of specialist multidisciplinary knowledge. In addition, the cost-effectiveness of advanced theranostic approaches and their incorporation into standard oncology pathways are not well established, particularly in low- and middle-income countries. Solving these problems will need coordinated efforts by clinicians, researchers, regulatory bodies and industry and government.

In this state-of-the-art review, we critically appraise the progress of oncologic theranostics from its historical basis to its contemporary function in precision oncology. We review biological rationale, key clinical data, established and emerging molecular targets, advances in personalized dosimetry, artificial intelligence and next generation radiopharmaceuticals, focusing on current controversies, implementation challenges and future research priorities. The review is to provide a balanced perspective on the benefits and limitations of theranostics, incorporating established knowledge and developing data as the field continues to revolutionize customized cancer therapy.

Figure 1. The Theranostic Paradigm in Precision Oncology



METHODS

Literature Searching Strategy

A complete literature search was undertaken using PubMed/MEDLINE, Embase, Scopus, Web of Science and Google Scholar to discover related papers on oncologic theranostics. The main search includes papers from January 2015 to December 2026, with crucial earlier works included to offer historical background. Search terms included a combination of Medical Subject Headings (MeSH) and free-text keywords, including theranostics, molecular imaging, radiopharmaceutical therapy, PET/CT, PET/MRI, SPECT/CT, PSMA, somatostatin receptor, PRRT, lutetium-177, actinium-225, fibroblast activation protein (FAP), CXCR4, HER2, radiomics, artificial intelligence, and personalized

dosimetry. Boolean operators were used to enhance retrieval and reference lists of key publications, international recommendations and consensus statements were hand-searched for further relevant studies.

Selection and Synthesis of Evidence

This article is a narrative review; formal systematic review techniques and meta-analysis were not conducted. Evidence was selected according to methodological quality, clinical relevance, scientific impact and contribution to the field, with priority given to randomised controlled trials, multicentre studies, pivotal phase II/III trials, international guidelines, consensus statements and high-quality reviews. Conflicting evidence was critically appraised based on study design, methodological constraints and sources of heterogeneity rather than stated outcomes.

The literature was thematically synthesized on the biological basis of theranostics, established and emerging clinical applications, landmark trials, novel molecular targets, personalized dosimetry, artificial intelligence, radiopharmaceutical innovations, implementation challenges and future directions. Special attention was given to evidence impacting recommendations from organizations such as SNMMI, EANM, NCCN and ESMO while emphasizing knowledge gaps and areas needing more inquiry.

Methodology Limitations

Given the narrative nature of this review, no formal risk-of-bias assessment was performed, nor were studies scored for quality, nor data quantitatively synthesized. We made every attempt to include the most influential and methodologically solid research, although expert judgment inevitably enters study selection and interpretation. Thus, the findings should be interpreted in light of the evolving evidence base, especially in areas of rapid development where high-quality comparative and long-term clinical data are lacking.

BIOLOGICAL FOUNDATION OF THERANOSTICS

Theranostics is based on the combination of molecular imaging and targeted radionuclide therapy with a common biological target. Unlike conventional oncology where patient selection is performed on the basis of morphological or histological classification, theranostics utilizes tumor-specific genetic changes to select patients, give treatment and measure response in a single framework of precision medicine.

The malignant transformation leads to the modification of gene expression, receptor density, metabolism and tumor microenvironment, therefore generating molecular targets that are selectively expressed in cancer cells. These targets are exploited by radiolabeled ligands for diagnostic imaging and therapeutic radionuclide administration, allowing for non-invasive confirmation of target expression prior to therapy . This technique improves patient selection, lowers needless toxicity and increases therapeutic precision. However, expression of the target alone is not enough to predict therapeutic effect, as tumor heterogeneity, receptor dynamics and radiopharmaceutical pharmacokinetics also play a role in treatment success.

Successful theranostic targets have high expression in tumor versus background, are biologically stable, and have good ligand accessibility. Examples that have been clinically validated include prostate-specific membrane antigen (PSMA) in prostate cancer and somatostatin receptor subtype 2 (SSTR2) in neuroendocrine tumors. Besides receptor expression, ligand properties, including binding affinity, internalization, intracellular retention and metabolic stability, are key drivers of therapeutic efficacy and constitute major areas of study of radiopharmaceuticals.

The biological response is also influenced by the radionuclide chosen. β-emitting isotopes like ^177Lu and ^90Y generate a cross-fire effect, which is beneficial for heterogeneous or bulky tumors. α-emitters like ^225Ac and ^212Pb emit high-linear-energy-transfer radiation over a short distance, resulting in dense DNA double-strand breaks with minimal collateral damage. Alpha-particle therapy has demonstrated promise in resistant malignancies; however, long-term

safety, optimal dosimetry and comparative clinical benefit of alpha-particle therapy are still under investigation, emphasizing the need for prospective randomized studies. Therapeutic efficacy beyond direct DNA damage. Radionuclide therapy also causes apoptosis, vascular damage, senescence, and immunogenic cell death, which provides a biological foundation for combining theranostics with immune checkpoint inhibitors and other systemic medicines . However, the clinical evidence for these combinations is in its infancy, and optimal sequencing and patient selection procedures have yet to be determined.

One of the main advantages of theranostics is the characterization of whole-body tumor heterogeneity . Unlike single-site biopsies, molecular imaging assesses target expression across all lesions, which facilitates better treatment selection, prognostication, and tracking of treatment response. Quantitative imaging biomarkers, including standardized uptake value (SUV), metabolic tumor volume (MTV) and radiomics characteristics combined with artificial intelligence may further refine patient categorization. However, the main barriers to clinical use are the heterogeneity of acquisition techniques, minimal external validation, and the lack of standardized analysis pipelines.

While significant advances have been made, some biological difficulties remain such as temporal variations in receptor expression, acquired resistance, heterogeneous biodistribution of radiopharmaceuticals, and complicated tumor and immune microenvironment interactions. Bridging these knowledge gaps through the integration of molecular biology, radiobiology, computational science, and translational research will be critical for the development of next generation theranostic methods and the expansion of their therapeutic impact.

CURRENT CLINICAL APPLICATIONS OF THERANOSTICS

Neuroendocrine Tumors

The most mature and well recognized use of oncologic theranostics is the treatment of neuroendocrine tumors (NETs). Most well-differentiated gastroenteropancreatic NETs over-express the somatostatin receptor subtype 2 (SSTR2), which allows sensitive molecular imaging with ^68Ga-DOTATATE, ^68Ga-DOTATOC, or ^64Cu-DOTATATE PET/CT and the selection of patients for peptide receptor radionuclide therapy (PRRT). This imaging-guided method is an example of precision oncology, as it confirms that the target is expressed before treatment.

The therapeutic counterpart, ^177Lu-DOTATATE PRRT, selectively delivers β-radiation to SSTR-positive tumor cells after receptor-mediated internalization. Compared to older ^90Y-based therapies, ^177Lu offers a better efficacy-to-toxicity ratio, with better dosimetric properties and lower renal toxicity.

The landmark NETTER-1 experiment showed that ^177Lu-DOTATATE is the standard of therapy for progressive, SSTR-positive midgut NETs with significant benefits in progression-free survival, objective response rates, and quality of life compared to high-dose octreotide. Long-term follow-up showed lasting disease management and an acceptable safety profile, leading to regulatory approval and inclusion in international standards. Subsequent observational studies have supported its treatment in pancreatic and bronchial NETs, while high-quality randomized evidence beyond midgut tumors is rare.

Patient selection is still critical and depends on appropriate receptor expression on PET/CT, assessment of tumor differentiation, renal function, bone marrow reserve and performance status. PRRT is well tolerated and transient hematopoietic toxicity is the most prevalent side event, whereas severe nephrotoxicity has become uncommon with modern amino acid renal protection. Rare long-term problems such as myelodysplastic syndrome and acute leukemia require continuous surveillance, particularly after repeated treatment cycles.

It has a well-established role, but still a number of unanswered questions. Further research is required to determine the best sequencing of PRRT with systemic therapy, the benefit of customized dosimetry compared to fixed dosage regimens,

retreatment techniques and the impact of combination regimens. Innovative techniques, e.g. the use of alpha-emitting radionuclides, may improve results in resistant disease, although there is yet no convincing randomized data. Thus, NETs remain the gold standard for successful theranostics, but further improvement of treatment techniques is necessary to optimize long-term efficacy and safety.

Prostate Cancer

Oncologic theranostics has become the most rapidly developing application in prostate cancer, with the success of prostate-specific membrane antigen (PSMA)-targeted imaging and radioligand therapy. PSMA is overexpressed in advanced, metastatic and castration-resistant prostate cancer and its receptor-mediated internalization permits longer intracellular retention of radiolabeled ligands, making it a suitable target for diagnostics and therapy.

The advent of PSMA PET/CT with either ^68Ga-PSMA-11 or ^18F-DCFPyL has revolutionized disease staging and recurrence detection with metastatic lesions detected with significantly higher sensitivity than conventional imaging. PSMA PET also acts as a predictive biomarker beyond diagnosis by validating target expression and selecting patients most likely to benefit from PSMA-directed radioligand therapy, which reflects the theranostic principle of imaging-guided treatment selection.

The therapeutic equivalent, 177Lu-PSMA-617, delivers β-radiation specifically to PSMA-expressing tumor cells with limited exposure of the surrounding tissue. The landmark VISION trial demonstrated significant improvements in overall survival, radiographic progression-free survival, prostate-specific antigen response, and quality of life in metastatic castration-resistant prostate cancer (mCRPC) patients, establishing ^177Lu-PSMA-617 as a standard of care after androgen receptor pathway inhibition and taxane chemotherapy . The TheraP trial also revealed improved PSA responses and a better toxicity profile compared to cabazitaxel and the PSMAfore study points to the advantage of initiating radioligand therapy earlier in the disease phase. Together, these data support an increasing importance of PSMA-targeted therapy in the therapeutic continuum.

But despite these gains, some limits remain. Tumor heterogeneity and variable PSMA expression, particularly in tumors with neuroendocrine differentiation or PSMA-negative metastatic clones, can adversely affect therapeutic efficacy . Dual-tracer imaging using FDG PET may reveal biologically aggressive PSMA-negative illness that is likely to be refractory to radioligand therapy. Poorly understood resistance mechanisms such as downregulation of PSMA expression, altered receptor trafficking, increased DNA repair, and clonal evolution are active areas of inquiry.

Overall, ^177Lu-PSMA therapy is generally well tolerated with xerostomia and mild to severe hematological toxicity being the most prevalent adverse events, and clinically relevant nephrotoxicity is rare. Alpha-emitting radioligands like ^225Ac-PSMA show promise in ^177Lu-refractory patients, but their use is limited by availability of radionuclides, salivary gland toxicity, and the absence of long-term prospective data. Finally, while PSMA-targeted theranostics have transformed the management of advanced prostate cancer, there remain critical unanswered questions about ideal sequencing, combination with systemic therapies, personalized dosimetry, cost-effectiveness, and long-term outcomes. Addressing these difficulties in randomized trials will be critical to maximize therapeutic benefit and permit application to earlier stages of disease.

Differentiated Thyroid Cancer

Differentiated thyroid cancer (DTC) is the prototype and most durable example of oncologic theranostics. Prior to the era of precision oncology, radioactive iodine provided a compelling example of a single molecular target for disease localization as well as treatment. This NIS-based paradigm set the stage for the principles of molecular target validation, imaging-guided patient selection, and targeted radionuclide therapy that are the foundation of modern theranostics.

The maintenance of NIS expression in well-differentiated papillary and follicular thyroid carcinomas allows for the selective uptake of radioactive iodine, which can be exploited for diagnostic imaging, remnant ablation, adjuvant therapy, and treatment of metastatic disease. Radioiodine therapy is a mainstay of management and, for appropriately selected patients, provides the opportunity for long-term follow-up using serum thyroglobulin.

Therapeutic efficacy is highly dependent on tumor differentiation. Well-differentiated tumors are often sensitive to radioiodine, whereas dedifferentiation is linked to the loss of NIS expression and the development of radioiodine-refractory differentiated thyroid carcinoma (RAIR-DTC). Recent breakthroughs in redifferentiation therapy with BRAF and MEK inhibitors have proven the potential to reinduce radioiodine absorption in selected individuals, opening new therapeutic perspectives. But clinical experience is still limited and durable long-term benefit has still to be demonstrated. ^18F-FDG PET/CT complements radioiodine imaging in advanced disease via the well-recognized 'flip-flop' phenomenon, whereby radioiodine-negative tumors frequently show increased glucose metabolism. FDG PET is thus particularly useful in patients with elevated thyroglobulin levels and negative radioiodine scans by providing prognostic information and identifying patients unlikely to benefit from further radioiodine therapy.

While radioiodine therapy has a good long-term safety profile, high cumulative dose treatment may lead to salivary gland dysfunction, xerostomia, lacrimal damage, acute bone marrow suppression and, infrequently, subsequent cancers. As a result, current ATA, ETA, and NCCN guidelines recommend a risk-adapted approach to radioiodine, selectively treating patients who are most likely to benefit clinically and sparing those with low-risk disease from unnecessary treatment.

Despite decades of clinical success, there are still various hurdles such as optimum patient selection, personalized dosimetry, RAIR-DTC management and integration with targeted medicines. Moreover, although radioiodine continues to be the paradigm for successful theranostics, extending radionuclide therapy beyond NIS-dependent disease would necessitate validation of other molecular targets and high-quality prospective investigations. Thus, thyroid cancer remains not only the historical basis of theranostics but also a platform for the development of next-generation precision radionuclide therapies.

Bone Metastases

Bone-targeted radionuclide therapy is a unique application of theranostics that exploits the biology of osteoblastic activity rather than tumor-specific receptors. It is mostly utilized in patients with advanced malignancies, notably prostate cancer, in whom diffuse skeletal metastases cause discomfort, pathological fractures, spinal cord compression and reduced quality of life. Bone-seeking radiopharmaceuticals preferentially localize to sites of active bone remodeling, thus enabling focal irradiation of numerous metastatic lesions with limited exposure to the surrounding tissues.

Early β-emitting drugs like ^89Sr and ^153Sm-EDTMP were beneficial for palliation of pain but did not increase overall survival and resulted in substantial myelosuppression, thereby restricting their long-term clinical utility. A notable breakthrough was the development of the α-emitter ^223Ra-dichloride, which delivers high-linear-energy-transfer radiation with a relatively short tissue range, resulting in strong tumor cell death with minimal bone marrow toxicity.

The major ALSYMPCA study has demonstrated ^223Ra to be a standard of care in patients with symptomatic, bone-predominant metastatic castration-resistant prostate cancer (mCRPC) without visceral metastases. Treatment significantly increased overall survival, delayed symptomatic skeletal events and improved quality of life. Radionuclide therapy can offer both symptomatic alleviation and survival advantage. Therefore, international guidelines recommend ^223Ra in selected patients after multidisciplinary evaluation.

Despite clinical value, there are considerable restrictions. The ERA-223 trial demonstrated increased fracture risk when ^223Ra was coupled with abiraterone and prednisolone without concomitant bone-protective treatment, resulting to modifications in clinical practice and routine use of bisphosphonates or denosumab in suitable patients. Evidence for

bone-seeking radionuclides beyond metastatic prostate cancer, however, remains limited, and no comparable survival benefit has been found in breast cancer or other solid tumors. Further research are needed to define appropriate treatment sequencing, combination techniques, personalized dosimetry, and patient selection. New radiopharmaceuticals that target both the bone microenvironment and tumor-specific biomarkers may improve treatment accuracy further, although their clinical value is experimental.

Breast Cancer

With advances in molecular imaging and radiopharmaceutical development, breast cancer has become an emerging theranostic area. ^18F-FDG PET/CT is still the standard for staging and response assessment but does not give target-specific information for radionuclide therapy. Thus, theranostic research has selected actionable molecular targets that enable the whole-body assessment of tumor biology and targeted treatment.

Human epidermal growth factor receptor 2 (HER2) is the most studied target and is overexpressed in ~15–20% of breast tumors . Radiotracers such as ^89Zr-trastuzumab and ^64Cu-labeled trastuzumab derivatives offer non-invasive evaluation of HER2 expression in primary and metastatic lesions, bypassing the constraints of a single site biopsy, and allow for detection of spatial or temporal receptor heterogeneity. These imaging methods can potentially improve patient selection for HER2-directed therapy and provide complementary information to standard immunohistochemistry.

Another interesting target is fibroblast activation protein (FAP) produced by cancer-associated fibroblasts in the tumor microenvironment. In early trials, FAPI PET showed promising diagnostic performance and a strong tumor-to-background contrast, while FAP-targeted radioligand treatment offers a new approach by targeting the tumor stroma instead of directly targeting malignant cells. Additional investigational targets including GRPR, estrogen receptor (ER), CXCR4, PD-L1 and integrins further emphasize the biological heterogeneity of breast cancer and opportunities for receptor-specific imaging and therapy.

Despite these breakthroughs, breast cancer theranostics are still primarily experimental. Patient selection is difficult due to heterogeneous receptor expression across molecular subtypes, metastatic locales and treatment stages, and the sluggish pharmacokinetics of antibody-based tracers may limit clinical usefulness. Additionally, therapeutic radioligands have only shown early-phase study activity and their relevance compared to existing HER2-targeted therapies, such as monoclonal antibodies and antibody-drug conjugates, has not been established.

Progress will depend on prospective multicenter trials showing considerable gains in survival, quality of life, and cost-effectiveness. Additional advances in patient selection can be obtained through standardized imaging methods, optimization of ligand design, tailored dosimetry, and integration with artificial intelligence and genomic analysis. Breast cancer, while not yet as clinically mature as NETs or prostate cancer, is one of the most potential areas for expansion of theranostic uses outside the conventional receptor-driven malignancies.

Lung Cancer

Lung cancer is the biggest cause of cancer-related death globally, with significant genetic and clinical variability. The management of non-small cell lung cancer (NSCLC) has been altered by precision oncology, with genomic profiling and tailored medications, however theranostic applications are still in early research. Lung cancer, unlike prostate cancer or neuroendocrine tumors, lacks a molecular target that is universally expressed, requiring subtype-specific methods.

Emerging targets, such as fibroblast activation protein (FAP), have received much attention due to their high expression in cancer-associated fibroblasts in the tumor microenvironment. FAPI PET shows fast tumor uptake and high tumor-to-background contrast. Preliminary investigations indicate enhanced detection of primary and metastatic lesions in selected patients with respect to conventional ^18F-FDG PET. Therapeutically, FAP-targeted radioligands give the ability to target the tumour stroma rather than malignant cells alone, however clinical efficacy has to be demonstrated.

Another intriguing target is delta-like ligand 3 (DLL3) which is strongly expressed in most small cell lung cancers (SCLC) but weakly expressed in normal tissues. DLL3-directed radiopharmaceuticals have generated promising preclinical and early clinical data . Other investigational targets being evaluated for receptor-specific imaging and radionuclide therapy include CXCR4, mesothelin, integrin $\alpha v\beta 3$, and GRPR. These strategies combined reflect the biological diversity of lung cancer and highlight the need for future theranostic strategies to be built on individualized molecular profiling rather than a one-size-fits-all platform.

Notwithstanding these developments, ^18F-FDG PET/CT persists as the clinical standard for staging, therapy planning and response assessment. However, FDG represents tumor metabolism and not actionable molecular targets and cannot be used to directly guide radionuclide therapy. The shift from metabolic to receptor-specific imaging represents a major milestone in the development of clinically effective lung cancer theranostics.

Most of the existing evidence is derived from preclinical and early clinical investigations. Challenges for patient selection and therapeutic development include tumor heterogeneity, dynamic target expression, rapid disease progression, and lack of validated predictive biomarkers. Large prospective trials are therefore needed to prove the safety, efficacy and cost-effectiveness of developing radiopharmaceuticals and to define their function alongside surgery, radiation, targeted treatments and immunotherapy. Lung cancer offers an exciting opportunity for theranostics, but the effective translation into ordinary clinical practice will depend on the identification of solid molecular targets and high quality clinical evidence.

Glioblastoma and Other Central Nervous System Tumors

Glioblastoma (GBM) and other high grade central nervous system (CNS) tumors continue to be some of the most difficult cancers to treat because of extensive infiltration, substantial intratumoral heterogeneity, treatment resistance, and the blood-brain barrier (BBB) limiting drug delivery. GBM does not have a uniformly expressed molecular target like those found in neuroendocrine tumors or prostate cancer, rendering theranostic development mostly exploratory and reliant on customized molecular profiling.

Most notably, CXCR4, which is involved in tumor growth, angiogenesis and glioma stem cell maintenance, is one of several targets under intensive investigation. First results with CXCR4-directed PET tracers and therapeutic radioligands have been promising in preclinical and early clinical research . Other intriguing targets include fibroblast activation protein (FAP), integrin $\alpha v\beta 3$, epidermal growth factor receptor (EGFR) variations, interleukin-13 receptor $\alpha 2$ (IL13Rα2), and neurokinin-1 receptor, although none of these have yet showed significant clinical evidence for widespread use.
In neuro-oncology, molecular imaging already complements conventional MRI. Amino acid PET tracers as ^18F-FET, ^11C-methionine (MET) and ^18F-FDOPA improve tumor characterisation and can aid to differentiate recurrence from treatment-related alterations. While these tracers are not, per se, theranostic, they highlight the utility of functional imaging in biopsy guidance, treatment planning and response assessment, and lay the groundwork for future receptor-specific imaging.

Efficient distribution across the BBB is a fundamental hurdle to radiation therapy. Convection-enhanced delivery, focused ultrasound-mediated BBB breakdown, nanoparticle-based devices and smaller targeting ligands are some of the efforts to boost intracranial medication penetration. Radionuclide therapy is also being studied in combination with radiation, temozolomide, antiangiogenic drugs and immunotherapy, to exploit complimentary biological pathways.

Although experimental breakthroughs are promising, clinical translation is still restricted. Most data are based on preclinical studies or modest early phase research, and few randomised studies have shown a survival benefit. Tumor heterogeneity, target variability, barriers to transport across the BBB, and resistance mechanisms still pose obstacles to widespread clinical application. Future advances will rely on the identification of robust molecular targets, enhanced transport of drugs into the brain and confirmation of these strategies in well-designed, prospective clinical trials.

Glioblastoma is one of the most challenging diseases to cure, but also one of the most exciting opportunities for next generation theranostic innovation.

Hematologic Malignancies

Hematologic malignancies constitute an exciting yet comparatively under-investigated field of oncologic theranostics. Unlike solid tumors, many lymphoid and plasma cell neoplasms display homogeneously lineage-specific surface antigens and are readily accessible to circulating radiopharmaceuticals, making them excellent candidates for targeted radionuclide therapy. Nevertheless, the clinical uptake has been slower than that of neuroendocrine tumors and prostate cancer, despite good scientific explanation, because of the rapid breakthroughs in immunotherapy and cellular therapies.

CD20-directed radioimmunotherapy with 90Y-ibritumomab tiuxetan and 131I-tositumomab was the first clinical success in B-cell non-Hodgkin lymphoma (NHL). These agents combined specificity of monoclonal antibodies with targeted delivery of radiation and produced durable responses in selected patients with relapsed or refractory indolent lymphoma. However, their use declined because of logistical complexity, prolonged myelosuppression, reimbursement issues, and competition from highly effective rituximab-based regimens and CAR T-cell therapies. Although these medications are not widely used now, they demonstrated the notion of targeted radionuclide therapy in hematologic malignancies.

In addition to lymphoma, CXCR4 has emerged as a promising theranostic target in multiple myeloma, where it is involved in plasma cell homing, disease progression, and treatment resistance. Non-invasive receptor profiling can be achieved with PET imaging using CXCR4-directed tracers and initial clinical investigations with therapeutic radioligands showed promising activity in strongly pretreated patients. BCMA (B-cell maturation antigen), already established as a target for CAR T-cell and antibody-drug combination treatments, is also being explored for radiological imaging and treatment. Other targets including CD37, CD38, CD45 and CD123 are also under intense examination in preclinical and early clinical studies.

Despite these gains, there are a number of difficulties that impede routine adoption. Bone marrow irradiation remains the primary dose-limiting hazard and requires cautious patient selection, tailored dosimetry, and thorough hematology monitoring. Clinical experience is limited, however, α-emitting radionuclides may improve the therapeutic index by delivering highly localized radiation. Randomized comparative data are also lacking for most investigational radiopharmaceuticals and their appropriate integration with the constantly emerging immunotherapies yet to be determined.

Future advancement will require prospective multicenter trials, uniform dosimetry, and sensible combinatorial approaches with immunotherapy and cellular treatments. Although hematologic theranostics have not reached the same clinical maturity as NETs or prostate cancer, the availability of highly selective molecular targets and the continuing progress in radiopharmaceutical engineering position this as one of the most exciting frontiers for precision radionuclide therapy.

CLINICAL EVIDENCE SUPPORTING CONTEMPORARY THERANOSTICS

The growing amount of high-quality clinical evidence demonstrating that molecular imaging-guided radionuclide therapy improves clinically meaningful outcomes in selected cancers has driven the integration of theranostics into modern oncology. In the last 10 years, important randomized trials have shown that theranostics is an evidence-based therapy method that can lengthen survival, slow disease progression, improve symptom control and quality of life. These investigations are characterized by the use of molecular imaging as a predictive biomarker to limit treatment to patients with sufficient target expression, optimizing therapeutic efficacy and avoiding needless harm.

The strongest evidence is in neuroendocrine tumors and metastatic prostate cancers. The NETTER-1 trial demonstrated ^177Lu-DOTATATE as the standard of care for progressing somatostatin receptor-positive neuroendocrine tumors, with significant increases in progression-free survival, objective response and quality of life. Similarly, the phase III VISION trial demonstrated significant overall and radiographic progression-free survival benefits with ^177Lu-PSMA-617 in metastatic castration-resistant prostate cancer, whereas the TheraP trial showed a better biochemical response as well as a more favorable toxicity profile compared with cabazitaxel. More recently, the PSMAfore study has supported early use of PSMA-targeted therapy, demonstrating that radioligand treatment may be most successful before the development of advanced treatment resistance.

Alpha-particle treatment also has increasing evidence. The ALSYMPCA study showed that in patients with symptomatic bone-predominant metastatic castration-resistant prostate cancer, ^223Ra-dichloride increased overall survival, delayed skeletal-related events and improved quality of life. Importantly, this study extended the scope of theranostics by demonstrating that radionuclide therapy can target the tumor microenvironment in addition to tumor-specific receptors. Together these trials have established some key principles of modern theranostics such as (1) molecular target validation before therapy as a prerequisite for patient selection, (2) clinically meaningful benefits beyond imaging responses to include survival, symptom control and patient reported outcomes, and (3) radionuclide therapy shows an acceptable safety profile when administered in experienced multidisciplinary teams . Therefore, theranostic approaches are currently recommended for specific malignancies by worldwide organizations such as SNMMI, EANM, NCCN, and ESMO.

But these developments leave major gaps in evidence. Most randomized trials have been in advanced disease, and it remains unclear whether the ideal timing of radionuclide therapy is in earlier treatment settings. In general, trial participants have been highly selected, which may limit generalizability to ordinary practice. Furthermore, there is a lack of direct comparisons between competing radiopharmaceuticals, defined dosimetry techniques, verified response criteria, long-term safety data, and thorough cost-effectiveness evaluations. Many of these constraints are anticipated to be addressed by ongoing research examining alpha-particle treatment, novel molecular targets, individualized dosimetry, and combination tactics with immunotherapy and targeted medicines.

In conclusion, the current data base clearly supports theranostics as a key component of precision oncology in selected tumors, but also highlights the need for further refinement through prospective head-to-head trials and wider validation in the real-world setting. Future advancement will depend on not only expanding therapeutic indications, but also on optimizing patient selection, treatment sequencing and personalized treatment delivery.

Personalized Dosimetry: The Foundation of Precision Radionuclide Therapy

Personalized dosimetry is essential in precision radionuclide therapy, taking into account the large interpatient variations in radiopharmaceutical biodistribution, tumor absorption, organ function, and radiation sensitivity. Although molecular imaging allows for proper patient selection, most licensed radionuclide therapies are provided at set activities, despite a large variability in received radiation doses between patients. Therefore, the same treatment regimens may have different therapeutic effectiveness and toxicity, indicating the necessity of personalized treatment strategies.

Dosimetry is the calculation of radiation absorbed by tumours and normal tissues, based on quantitative imaging, pharmacokinetic modelling and computer techniques. PET/CT and SPECT/CT have enhanced the patient-specific assessment of radiopharmaceutical distribution. Voxel-based dosimetry enables three-dimensional characterization of dose heterogeneity within tumors. The accuracy of dose prediction and treatment planning has also increased with the advent of computational methods such as the Medical Internal Radiation Dose (MIRD) formalism and Monte Carlo simulations.

There is emerging clinical evidence for dosimetry-guided therapy. Large variety of tumor and organ absorbed doses was observed in studies on ^177Lu-DOTATATE peptide receptor radionuclide therapy (PRRT) and ^177Lu-PSMA radioligand therapy, even with the same given activity. Individualized dosimetry can improve the therapeutic index by enhancing

tumor irradiation, while minimizing exposure to dose limiting organs such as the kidneys, salivary glands, liver and bone marrow. Early studies also indicate relationships between the amount of tumor radiation absorbed and responsiveness to treatment, however globally agreed dosage thresholds have yet to be developed.

Bone marrow dosimetry is particularly hard due to complicated marrow structure, fluctuating tumor infiltration and imaging restrictions. Moreover, routine use of individualized dosimetry is inhibited by the necessity of several imaging time points, specialized software, trained personnel, and the absence of established protocols among institutions. Such efforts, like those made by EANM, SNMMI and the MIRD Committee to harmonize are therefore crucial to promote wider clinical implementation.

Artificial intelligence is projected to accelerate clinical deployment by automating organ segmentation, lesion delineation, kinetic modeling, and dose calculation while integrating imaging with clinical and genetic data to predict therapeutic response and toxicity. Most AI-based dosimetry systems, however, are still exploratory and need prospective validation before they can be used routinely. Similarly, while dosimetry driven therapy is biologically attractive, few definitive randomized trials have shown improved survival or lower toxicity compared to fixed activity regimens. Future studies should therefore focus on standardized techniques, clinically verified dose thresholds and prospective outcome-driven trials to establish individualized dosimetry as the standard of care in radionuclide therapy.

Artificial Intelligence and Digital Transformation: Redefining the Theranostic Ecosystem

The integration of complicated imaging, molecular, clinical, and dosimetric data into precision treatment regimens is fast revolutionizing theranostics by artificial intelligence (AI). Modern radionuclide therapy is increasingly multimodal information-driven, integrating quantitative PET/SPECT imaging, anatomical imaging, laboratory biomarkers, genomic profiling, and treatment history, which presents analytical hurdles beyond typical statistical approaches. Thus, AI has emerged as a crucial facilitator of data-driven precision oncology, supporting decision-making across the theranostic route from diagnosis and patient selection to treatment planning, response assessment and longitudinal follow-up.

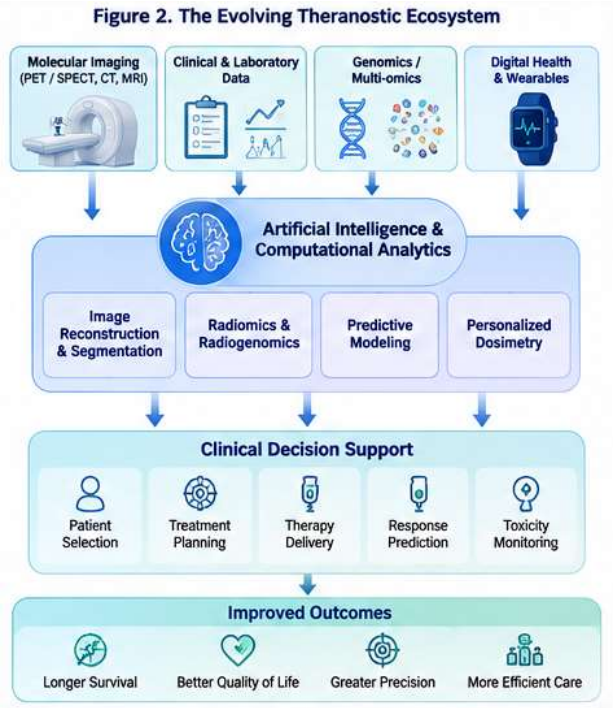
One of the earliest therapeutic uses of AI has been in the reconstruction and interpretation of images. Deep learning methods increase picture quality, reduce noise, cut acquisition times and permit lower radiotracer dosages while maintaining diagnostic accuracy. AI also permits automated lesion recognition, segmentation, and assessment of tumor burden, lowering observer variability and enhancing workflow efficiency. When used in conjunction with radiomics, machine learning has the ability to extract quantitative imaging aspects that correlate with tumor phenotype, receptor expression, treatment response and prognosis, hence providing a potential for more sophisticated patient classification than traditional image interpretation alone.

The use of AI is also predicted to be important in individualized radionuclide therapy. Automated organ segmentation, voxel-based dosimetry and kinetic modeling can greatly simplify the calculation of individualized dose, and predictive algorithms incorporating imaging, genomic and clinical data may improve the prediction of treatment response and treatment-related toxicity. These improvements provide the prospect of adaptive radionuclide therapy where the delivered activity is tailored based on individual patient characteristics and treatment response.

In addition to imaging, AI also contributes to the developing discipline of radiogenomics, which links imaging phenotypes with genomic and molecular traits to enable non-invasive evaluation of tumor biology. Integration of imaging with transcriptomic, proteomic and circulating biomarker data may further enhance patient selection and allow for longitudinal monitoring without recurrent tissue biopsies. These multimodal data streams could in the future be used to build digital twin models to mimic the evolution of disease and predict personalized treatment outcomes, although such applications remain primarily experimental.

Despite much promise, widespread clinical implementation is restricted. Most AI models have been trained on retrospective, single-center datasets and typically lack external validation across varied populations and imaging platforms. Other issues include diversity in acquisition techniques, poor model interpretability, regulatory ambiguity, data privacy, and potential for algorithmic bias. AI should be considered a clinical decision-support tool, not an independent decision-maker, and medical monitoring is relevant at this time.

Future advancement will require prospective multicenter validation, uniform reporting templates, transparent and explainable algorithms, and incorporation into routine clinical operations. AI has the potential to improve the accuracy, efficiency and personalization of theranostics, but its ultimate therapeutic usefulness will depend on demonstrating real gains in patient outcomes, not just computational performance.



Emerging Molecular Targets and Next-Generation Radiopharmaceuticals: Expanding the Horizons of Precision Oncology

The clinical success of somatostatin receptor (SSTR)- and prostate-specific membrane antigen (PSMA)-directed theranostics has encouraged the exploration of other molecular targets to broaden the application of radionuclide therapy to a broader spectrum of cancers. An ideal theranostic target should exhibit excellent tumor selectivity, low expression in normal tissues, favorable pharmacokinetics and repeatable radiopharmaceutical labeling. However, the rapid progress in molecular biology, radiochemistry and translational oncology has hastened the creation of several interesting targets, although most are still in early clinical investigation.

One of the most promising of these has been fibroblast activation protein (FAP). FAP is largely expressed by cancer-associated fibroblasts of the tumor microenvironment (TME) and is strongly expressed in many epithelial malignancies, unlike the common targets expressed on tumor cells. First investigations show promising tumor-to-background contrast with FAPI PET and therapeutic radioligands with ^177Lu, ^90Y and ^225Ac are tested in the clinic. Targeting the tumor stroma in addition to malignant cells may overcome limitations related to tumor heterogeneity, although durable clinical benefit has not been established yet.

Other key targets for study are HER2, CXCR4 and gastrin-releasing peptide receptor (GRPR). Radiolabeled HER2-directed antibodies, affibodies and nanobodies provide whole-body characterization of receptor heterogeneity and may augment current HER2-targeted therapy in resistant disease. CXCR4-directed imaging and therapy have shown promise in hematologic malignancies. GRPR-directed radiopharmaceuticals may offer an alternative or complementary approach in prostate and breast cancers, particularly in tumors with heterogeneous PSMA expression. Other targets such as integrin $\alpha v\beta 3$, carbonic anhydrase IX (CAIX), mesothelin, DLL3 and neurotensin receptor are in preclinical and early phase clinical research.

Progress in radiopharmaceutical engineering is keeping pace with this and opening up therapeutic opportunities. Novel ligand platforms such nanobodies, affibodies, antibody fragments, cyclic peptides, aptamers and small-molecule inhibitors can offer better tumor penetration, faster blood clearance and lower background activity than conventional monoclonal antibodies. Simultaneously, the focus is turning not just beyond ^177Lu to α-emitting radionuclides such as ^225Ac, ^212Pb and ^213Bi but also towards new β-emitters such as ^161Tb, permitting the selection of the isotope according to tumor biology and lesion features. Bispecific radiopharmaceuticals and multifunctional nanotheranostic platforms further try to address tumor heterogeneity by simultaneously targeting various biological pathways.

The rapid progress does not easily translate into routine clinical practice. Most novel radiopharmaceuticals are mainly supported by preclinical or early phase clinical studies with little randomized evidence for superiority over conventional medicines. Moreover, successful clinical translation requires not only target specificity, but also favourable pharmacokinetics, scalable production of radionuclides, standardised manufacturing, regulatory approval and cost-effectivity. Variability in target expression between tumor types and during disease evolution thus increases the usefulness of molecular imaging for patient selection.

Future advances will probably combine new molecular targets with alpha-particle therapy, personalized dosimetry, artificial intelligence-assisted ligand design, and radiogenomics. However, the ultimate success of next-generation theranostics will depend on establishing compelling comparative clinical evidence indicating major gains in survival, quality of life and healthcare value rather than technological innovation alone.

Table 1. Established and Emerging Theranostic Targets in Oncology

Target	Main Cancer Types	Imaging Agent (Examples)	Therapeutic Agent (Examples)	Clinical Status
Somatostatin receptors (SSTR)	Neuroendocrine tumors	^{68}Ga-DOTATATE	^{177}Lu-DOTATATE	Established
PSMA	Prostate cancer	^{68}Ga-PSMA-11	^{177}Lu-PSMA-617 ^{225}Ac-PSMA	Established
Sodium-iodide symporter	Differentiated thyroid cancer	^{123}I / ^{131}I	^{131}I	Established
FAP	Multiple solid tumors	^{68}Ga-FAPI	^{177}Lu-FAPI ^{225}Ac-FAPI	Early clinical
HER2	Breast, gastric and other cancers	^{68}Ga-trastuzumab fragments	^{177}Lu-HER2 ^{225}Ac-HER2	Early clinical
CXCR4	Hematologic and solid tumors	^{68}Ga-pentixafor	^{177}Lu-pentixather ^{225}Ac-pentixafor	Early clinical
GRPR	Prostate, breast, gastrointestinal	^{68}Ga-RM2	^{177}Lu-RM2	Investigational

Alpha-Particle Therapy: Redefining the Therapeutic Index of Radionuclide Therapy

Alpha-particle treatment is one of the most promising recent advancements in radionuclide therapy and has the ability to overcome the limitations of conventional %β%-emitters radiopharmaceuticals. Unlike β-particles, alpha particles have high LET and a very narrow range in tissue (<100 μm) to produce dense, irreversible DNA double strand breaks while sparing surrounding normal tissues from irradiation. These features make alpha emitters particularly appealing for the treatment of micrometastatic illness, heterogeneous malignancies and tumors resistant to traditional radionuclide therapy.

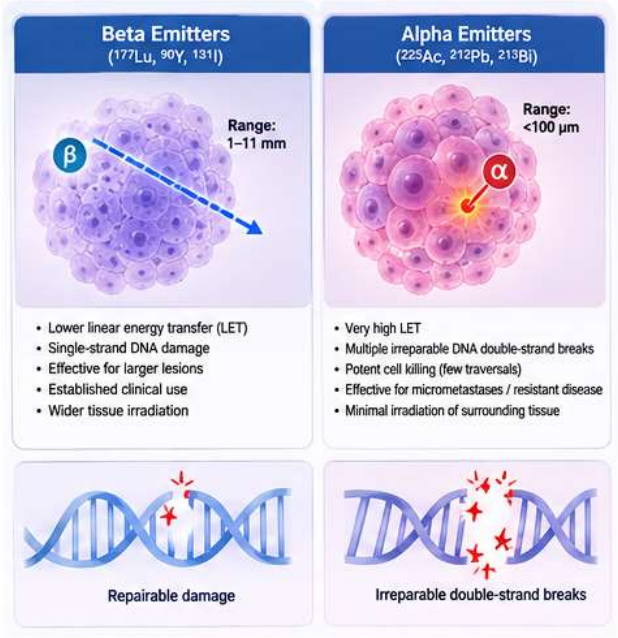
Of the radionuclides now under investigation, 225 Ac has been shown to have the most clinical interest. Early experiences with ^225Ac-PSMA have demonstrated encouraging biochemical and imaging responses in patients with metastatic castration-resistant prostate cancer, including those with progression after ^177Lu-PSMA therapy, indicating that alpha therapy may overcome resistance to β-emitting radioligands. Other experimental alpha emitters include ^212Pb, ^213Bi, ^211At and ^227Th are under evaluation in a spectrum of solid and hematologic cancers, targeting targets such as somatostatin receptors, HER2, FAP, CXCR4, CD33 and mesothelin.

Notwithstanding these favorable results, many problems impede widespread clinical acceptance. Xerostomia is the major dose-limiting hazard of ^225Ac-PSMA, reflecting physiological PSMA expression in salivary glands, and efficient gland-protective measures are still to be found. Other challenges are the restricted production of radionuclides, complicated radiochemistry, redistribution of daughter radionuclides and unavailability of defined microdosimetric methodologies. In addition, the existing clinical data are mainly from small, single-arm or early-phase investigations, and the evidence on long-term safety and comparative efficacy remains limited.

Alpha-particle treatment is also being investigated in combination with immune checkpoint inhibitors, DNA damage response inhibitors, PARP inhibitors and external beam radiation. High-LET radiation may promote antitumor immunity by inducing immunogenic cell death and modifying the tumor microenvironment, providing a strong biological basis for combination strategies. However, these techniques remain exploratory and require prospective study of their optimum sequencing and toxicity profiles.

Moving forward will involve increasing radionuclide production capacity, enhancing the stability of chelators, improving personalized dosimetry, and conducting adequately powered randomized clinical trials. The combination with artificial intelligence, quantitative imaging, and predicted dosimetry may improve further patient selection and treatment planning. Although alpha-particle therapy has the potential to improve the therapeutic index of radionuclide therapy, its ultimate role will depend on demonstrating sustained clinical benefit, acceptable toxicity and cost-effectiveness relative to established beta-emitting radiopharmaceuticals.

Figure 3. Beta vs Alpha Emitters: Physical and Biological Comparison



Combination Treatment Strategies: Integrating Theranostics into Multimodal Cancer Care

Theranostics is increasingly being employed as part of a multi-modal cancer care rather than a stand-alone treatment. Tumor progression is driven by genetic heterogeneity, clonal evolution, and interactions with the tumor microenvironment; hence, durable disease control is generally achieved by combining targeted radionuclide therapy with surgery, systemic therapy, immunotherapy, or external beam radiotherapy (EBRT). These tactics try to exploit complimentary biological pathways, while keeping toxicity within acceptable limits.

Immune checkpoint inhibitors (ICIs) have been the most explored of the new combos. Besides direct cytotoxicity, radionuclide therapy may cause immune cell death, improve antigen presentation and modify the tumor microenvironment, offering a justification for combination with PD-1, PD-L1 and CTLA-4 inhibitors. Early phase trials in prostate cancer, neuroendocrine tumors and other solid malignancies reveal potential synergy, but strong survival data are not yet available and the best time of combination therapy is not yet identified.

Another potential approach is the combination of radionuclide therapy with inhibitors of DNA damage response (DDR), especially PARP inhibitors. Radionuclide therapy induces DNA strand breaks and inhibition of DNA repair can lead to increased radiosensitivity, especially in tumors with homologous recombination defects such as BRCA1/2 or ATM mutations. A number of active trials are testing ^177Lu-PSMA with PARP inhibition in metastatic prostate cancer, however the long-term efficacy and safety remain unknown.

Targeted therapy may further boost theranostic effectiveness through enhanced target expression or radiosensitivity. For example, BRAF and MEK inhibitors have been used to restore sodium-iodide symporter expression in radioiodine-refractory differentiated thyroid cancer, resulting in renewed responsiveness to radioiodine therapy. Combinations with androgen receptor inhibitors, HER2-targeted treatments, and other molecular medicines are also being actively investigated.

Theranostics is also a useful adjunct to external beam radiation (EBRT) and surgery. EBRT is useful for local management of bulky or symptomatic lesions. Radionuclide therapy targets widespread microscopic disease depending on expression of molecular targets. Preoperative molecular imaging can aid surgical planning, and postoperative radionuclide therapy can ablate residual or metastatic illness, highlighting the relevance of theranostics in multidisciplinary cancer care.

Combination techniques are biologically well-justified, but are still primarily experimental. Optimal sequencing, cumulative toxicity, customized dosimetry, and patient selection have not been established and overlapping hematologic, renal and salivary gland toxicities necessitate close monitoring. Most of the data available are from pre-clinical research or early phase clinical trials with few randomized studies showing a survival or quality of life benefit. Future advancement will depend on the use of biomarker-driven trial designs, standardization of dosimetry and prospective comparison studies that specify which patients benefit most from specific combinations while keeping an acceptable safety profile.

Table 2. Key Opportunities and Challenges in Theranostic Development

Domain	Key Opportunities	Major Challenges
Radiopharmaceuticals	• New targets • Alpha emitters • Multifunctional ligands	• Production and supply • Complex radiochemistry • Regulatory requirements
Quantitative Imaging & Dosimetry	• Personalized treatment • Adaptive therapy • Better safety	• Standardization • Validation of dose–response • Clinical implementation
Artificial Intelligence	• Automated analysis • Predictive modeling • Decision support	• Generalizability • Interpretability • Data quality and privacy
Combination Therapy	• Synergistic efficacy • Overcome resistance • Broader indications	• Optimal sequencing • Overlapping toxicities • Evidence from RCTs
Clinical Translation	• Wider access • Cost-effective care • Improved outcomes	• Infrastructure • Workforce training • Global equity

Abbreviation: RCTs, randomized controlled trials.

CLINICAL TRANSLATION: SAFETY, TOXICITY, AND BARRIERS TO IMPLEMENTATION

The transition of theranostics into ordinary oncology will hinge on efficacy and safety, defined clinical routes, a stable radionuclide supply, specialized infrastructure and equal access. Although randomized trials have demonstrated meaningful gains in survival, disease control, and quality of life for some malignancies, logistical, regulatory, and economic obstacles pose a significant barrier to broader deployment.

Toxicity and Safety

Targeted radionuclide therapy selectively delivers radiation to malignant tissue. Physiologic expression of molecular targets in normal organs always leads to off-target radiation exposure. Toxicity depends on the target biology, radionuclide properties, delivered activity, cumulative dose, pharmacokinetics and baseline organ performance.

Hematologic toxicity remained the most common side event, especially in patients with significant skeletal metastases, prior chemotherapy or limited bone marrow reserve, underscoring the significance of cautious patient selection and longitudinal monitoring. A significant limitation of peptide-based therapeutics has been renal toxicity, which has been dramatically decreased in the past by amino acid nephroprotection, improved ligand design and optimized treatment regimens. Patients with pre-existing renal impairment need individual risk assessment. Xerostomia is the main dose-limiting effect of PSMA-directed therapy, particularly with ^225Ac-PSMA where harm to the salivary glands can have a major impact on quality of life. Other adverse effects are generally uncommon but still need ongoing long-term monitoring and include fatigue, nausea, transient gastrointestinal symptoms, and rare therapy-related myelodysplastic syndrome or acute leukemia. Importantly, patient-reported outcomes have consistently shown that improvements in disease control are typically accompanied by meaningful benefits in quality of life, highlighting the relevance of patient-centered assessment.

Infrastructure & Workforce

Successful theranostic programs require dedicated radiopharmacy facilities, quantitative imaging systems, radiation safe treatment environments, medical physics support and multidisciplinary teams of nuclear medicine physicians, oncologists, radiologists, surgeons, radiopharmacists, medical physicists, specialist nurses and radiation safety personnel. These infrastructure and manpower needs remain substantial obstacles, especially in healthcare systems without established nuclear medicine services, stressing the need for greater training and interdisciplinary collaboration.

Radionuclide Supply and Health Policy

The growing clinical demand has exposed critical weaknesses in global radionuclide manufacturing. Many of the key isotopes (^177Lu, ^68Ga and especially ^225Ac) rely on limited production capacity and supply disruption remains a

common hurdle to clinical growth. Investment in reactor technology, accelerator-based production and robust international supply networks will therefore be key for sustainable expansion.

Theranostic medicines are associated with high upfront costs, but their utility goes well beyond the procurement of drugs as they allow better patient selection, slow disease progression, decrease healthcare utilization, and perhaps improve quality-adjusted survival. However, reimbursement rules differ greatly among health care systems and detailed cost-effectiveness assessments are lacking. Strong economic evidence will be critical to informing decisions around reimbursement and fostering wider uptake.

CHALLENGES IN GLOBAL AND REGULATORY IMPLEMENTATION

Many existing regulatory regimes have not kept pace with rapid breakthroughs in radiopharmaceutical development. The standardization of manufacturing standards, imaging protocols, dosimetry methodologies, response criteria, and reporting standards by organizations such as the IAEA, EANM, and SNMMI is critical to ensure reproducibility across institutions and facilitate multicenter clinical trials.

One of its biggest concerns continues to be access to theranostics. Advanced molecular imaging and radionuclide therapy are centralized in high-resource centers, and the restricted infrastructure, staff shortages, regulatory complexity, treatment costs, and isotope availability continue to impede access in many low- and middle-income nations. International cooperation, regional production of radionuclides, technology transfer, workforce development and sustainable health policies will be needed to address these inequities.

Critical Perspective

Despite impressive scientific progress, the major challenge for next generation theranostics remains clinical translation. Future success will not only depend on the development of new radiopharmaceuticals, but also on the standardization of dosimetry, the strengthening of long-term safety surveillance, the assurance of a reliable supply of radionuclides, the generation of robust cost-effectiveness data, and the expansion of equitable global access. Without overcoming these operational challenges, theranostics' therapeutic impact will remain restricted, despite ongoing technological improvement.

FUTURE PERSPECTIVES: THE NEXT DECADE OF PRECISION THERANOSTICS

Theranostics, which used to be a niche application of nuclear medicine, is now a major component of precision oncology, merging molecular imaging, targeted radionuclide therapy, quantitative dosimetry, and computational medicine. The coming decade will probably bring fewer incremental enhancements to existing radiopharmaceuticals, and greater innovations that enhance personalization, extend therapeutic indications and enable worldwide application. There are some events that are especially likely to affect the future of the field.

Expansion beyond existing molecular targets

Although PSMA and somatostatin receptor theranostics have revolutionized the treatment of prostate cancer and neuroendocrine tumors, most malignancies lack approved therapeutic targets. Among the developing candidates, fibroblast activation protein (FAP) is especially interesting due to its ubiquitous expression across many epithelial malignancies and the capacity to target the tumor microenvironment, rather than malignant cells alone. Future development of radiopharmaceuticals will also include nanobodies, bispecific ligands, scaffold proteins and synthetic biomolecules with better pharmacokinetic properties. However, clinical implementation would require randomized trials demonstrating a significant benefit in survival, quality of life and cost effectiveness, not just imaging performance.

Alpha-Particle Therapy

One of the most important therapeutic developments in radionuclide therapy is alpha-emitting radionuclides. Because of their high linear energy transfer and short tissue range they are potentially able to overcome the resistance to conventional β-emitting radiopharmaceuticals, especially in little residual illness and in treatment refractory malignancies. However, challenges remain before the widespread adoption of alpha therapy, including radionuclide production, toxicity mitigation, dosimetric standardization and limited prospective clinical evidence. More biological innovation will be as crucial as expanding dependable isotope production.

Artificial Intelligence and Adaptive Personalized Dosimetry

Clinical practice may be reshaped by the move from fixed-activity administration of radionuclides to adaptive, patient-specific therapy. The integration of artificial intelligence with quantitative imaging, voxel-level dosimetry, laboratory biomarkers and clinical data may enable the dynamic adjustment of administered activity, treatment intervals and radionuclide selection throughout therapy. Although these technologies promise to improve precision, prospective validation and transparent clinical decision support systems are necessary before routine use.

Radiogenomics and Integrating Multi-Omics

In the future, treatment will likely depend on more than just which receptors are expressed. Molecular imaging in conjunction with genomic, transcriptomic, proteomic, metabolomic and radiomic data may allow for more precise prediction of radiosensitivity, therapeutic resistance and treatment response. Such multimodal techniques could provide for the first time personalized radiopharmaceutical selection and help identify patients more likely to benefit from combo therapy. However, external validation and defined analytical frameworks will be needed before general clinical application.

Combination Precision Therapies

Theranostics are increasingly expected to be used as part of integrated precision oncology rather than as a separate therapy approach. Among the combination treatments, radionuclide therapy plus immune checkpoint inhibitors seems particularly promising, since radiation may boost anti-tumor immunity through immunogenic cell death and modification of the tumor microenvironment. Since the current evidence is mostly limited to preclinical and early-phase clinical studies, further research should be directed at determining the appropriate sequencing, predictive biomarkers, and management of toxicities.

Global Clinical Practice translation

The future of theranostics will be decided not only by scientific development. Reliable production of radionuclides harmonized regulatory frameworks, standardized dosimetry, workforce development and fair access across varied health care systems will be needed for sustainable growth. Investment in isotope production, particularly for alpha emitters, alongside international collaboration and evidence-based reimbursement policies will be essential to ensure that advances in precision radionuclide therapy benefit patients globally rather than being restricted to specialized centers.

Future Prospects

The future of theranostics is the integration of molecular imaging, targeted radionuclide therapy, artificial intelligence, radiogenomics, and precision dosimetry into a continually evolving clinical ecosystem. Rather of replacing existing cancer therapies, theranostics will supplement surgery, systemic therapy, immunotherapy and external beam radiotherapy more and more, through biologically guided treatment selection. Success will ultimately rely on not only technology innovation but also on establishing enduring therapeutic benefit, cost-effectiveness and equitable worldwide deployment. If these problems are properly handled, theranostics will become one of the pillars of precision oncology in the next decade.

Table 3. Future Directions for Precision Theranostics

Priority Area	Expected Impact
Expanded molecular targets (FAP, HER2, CXCR4, others)	• Treat broader range of cancers • Overcome resistance mechanisms
Alpha-particle therapy	• Higher therapeutic efficacy • Effective for micrometastatic / resistant disease
AI and multi-omics integration	• More precise patient selection • Real-time adaptive treatment • Digital twin–based decision support
Personalized dosimetry	• Maximize tumor dose • Minimize toxicity • Improve safety and outcomes
Rational combination strategies	• Synergistic efficacy with ICIs, DDR inhibitors, targeted therapy and EBRT
Global implementation	• Standardization • Scalable production • Equitable access worldwide

CONCLUSION

Theranostics has revolutionized cancer by merging molecular imaging with targeted radionuclide therapy into a cohesive precision medicine framework. By connecting diagnosis, patient selection, therapy, and response evaluation via common molecular targets, cancer management has transitioned from an anatomy-centric approach to scientifically informed, personalized care. Proven applications in neuroendocrine tumors, prostate cancer, and differentiated thyroid carcinoma have shown significant enhancements in survival, disease management, and quality of life, affirming theranostics as a fundamental aspect of comprehensive cancer treatment. Simultaneously, novel targets such fibroblast activation protein (FAP), HER2, CXCR4, and GRPR suggest significant promise for broadening radionuclide therapy to encompass a greater variety of cancers.

Advancements in theranostics are progressively propelled by innovations that extend beyond the mere manufacture of radiopharmaceuticals. Customized dosimetry, artificial intelligence, quantitative imaging, radiogenomics, and alpha-particle therapy are transforming treatment strategies and facilitating more accurate, individualized radionuclide therapy. Nonetheless, considerable obstacles persist prior to the broad adoption of these advancements. Dependable radionuclide generation, uniform dosimetry, rigorous comparative clinical studies, extensive safety data, economic viability assessments, regulatory alignment, and fair worldwide accessibility are essential concerns for forthcoming research and clinical applications.

Ultimately, the trajectory of theranostics will hinge on both the identification of novel molecular targets and the effective integration of scientific breakthroughs into standard clinical practice. Through sustained interdisciplinary cooperation and the application of evidence-based practices, theranostics is set to emerge as a fundamental component of precision oncology, establishing a system where molecular profiling directly informs personalized cancer therapies and enhances results for a growing patient demographic.

Declaration on Ethical AI use

Artificial intelligence-assisted techniques were employed just for language improvement, structural organization, and editorial help. The literature selection, data interpretation, critical appraisal and all scientific conclusions were independently completed and validated by the authors using primary peer-reviewed sources. The authors are fully responsible for the accuracy, originality and integrity of the paper in accordance with current ICMJE criteria.

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