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Nano-Radiopharmaceuticals in Cancer Treatment: A Systematic Review of Clinical Applications and Implications for Oncology Pharmacy Practice

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Abstract:

- ***Background***

The convergence of nanotechnology and radiopharmaceutical science represents a transformative approach in precision oncology. By combining nanoscale delivery systems with therapeutic radioisotopes, nano-radiopharmaceuticals achieve targeted tumor irradiation while minimizing off-target toxicity. Despite growing clinical adoption, systematic assessments integrating clinical efficacy, safety, and pharmacy practice implications remain limited.

- ***Objective***

To systematically review the clinical applications, therapeutic efficacy, safety outcomes, and pharmacy practice considerations of nano-radiopharmaceuticals currently approved or in development for cancer treatment.

- ***Methods***

A systematic search was conducted in PubMed, EMBASE, Cochrane Library, Web of Science, and ClinicalTrials.gov from January 2015 to August 2025, following PRISMA guidelines. Human clinical trials reporting therapeutic applications of nano-radiopharmaceuticals were included. Two reviewers independently screened and extracted data on study characteristics, efficacy outcomes, safety profiles, manufacturing requirements, and pharmacy practice implications.

- ***Results***

Of 3,247 records screened, 89 studies involving 12,456 patients were included. Agents approved for clinical use include ibritumomab tiuxetan (Zevalin®), lutetium-177 dotatate (Lutathera®), lutetium-177 PSMA-617 (Pluvicto®), and yttrium-90 microspheres. Overall response rates ranged from 23% to 83%, with hematologic malignancies showing superior activity (median ORR 78%) compared with solid tumors (median ORR 42%). Grade 3–4 toxicities occurred in 15–45% of patients, mainly hematologic. Implementation required specialized facilities in nearly 90% of institutions, with average preparation times of 2.5–4.8 hours and costs per treatment course ranging from $15,000 to $85,000.

- ***Conclusion***

Nano-radiopharmaceuticals have demonstrated substantial clinical efficacy with manageable toxicity profiles across multiple cancer types. Their integration into oncology practice demands significant pharmacy infrastructure, specialized training, and rigorous quality control. Continued research is needed to refine patient selection, enhance manufacturing efficiency, and establish cost-effectiveness frameworks.

Keywords: *Nano-Radiopharmaceuticals, Systematic Review, Oncology Pharmacy, Targeted Radiotherapy, Cancer.*

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I. INTRODUCTION

Cancer continues to represent one of the leading global causes of morbidity and mortality, with an estimated 19.3 million new cases and more than 10 million deaths worldwide in 2024 [1]. While systemic therapies such as chemotherapy and targeted small molecules have improved survival in many malignancies, their limited selectivity often results in significant toxicity and narrow therapeutic indices [2]. Novel therapeutic modalities that maximize tumor-specific delivery while minimizing systemic adverse effects are urgently required.

Nano-radiopharmaceuticals have emerged at the intersection of nanotechnology and nuclear medicine as highly promising agents in precision oncology [3]. Radiopharmaceuticals utilize radioisotopes for both diagnosis and therapy, offering the unique advantage of real-time imaging and targeted irradiation. The incorporation of nanotechnology into radiopharmaceutical design has addressed several limitations of conventional agents, including rapid systemic clearance, poor tumor penetration, and non-specific biodistribution [4].

These next-generation agents comprise a wide range of platforms. Antibody-radioisotope conjugates allow highly specific targeting of cell surface antigens, while liposomal or polymeric nanoparticles provide encapsulation strategies that improve circulation time and tumor uptake [5]. Passive targeting exploits the enhanced permeability and retention (EPR) effect characteristic of many solid tumors, whereas active targeting relies on molecular ligands or antibodies to achieve selective binding to tumor cells [6].

The clinical approval of lutetium-177 PSMA-617 (Pluvicto®) for metastatic castration-resistant prostate cancer in 2022, and its subsequent rapid global uptake, illustrates the clinical and commercial potential of this therapeutic class. Sales surpassed $1 billion within the first three quarters of 2024, highlighting the accelerated adoption of nano-radiopharmaceuticals and the expansion of research pipelines.

From the perspective of oncology pharmacy practice, these agents present both opportunities and challenges. Their preparation requires specialized radiation-shielded facilities, adherence to complex handling protocols, and extensive staff training [7]. The FDA has issued dedicated regulatory guidance for therapeutic radiopharmaceuticals, underscoring the need for rigorous quality control, individualized dosing regimens, and comprehensive safety monitoring [8].

Despite the growing clinical use of nano-radiopharmaceuticals, systematic reviews that integrate clinical efficacy, safety outcomes, and pharmacy practice considerations remain limited. To address this gap, we conducted a systematic review of published clinical trials and regulatory reports to evaluate the efficacy, toxicity, preparation requirements, and future directions of nano-radiopharmaceuticals in cancer treatment, with a particular focus on implications for oncology pharmacy practice.

II. METHODS

➢ *Protocol Registration and Reporting Standards*

This review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [9]. The review protocol was prospectively registered in the PROSPERO database (registration number to be provided upon manuscript acceptance).

➢ *Search Strategy*

A comprehensive literature search was performed across PubMed/MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, Web of Science, and ClinicalTrials.gov. The timeframe spanned January 1, 2015, to August 22, 2025, to capture contemporary developments in nano-radiopharmaceutical therapy.

The search strategy, developed in collaboration with a medical librarian, combined Medical Subject Headings (MeSH) and free-text terms. Core terms included: “radiopharmaceuticals,” “nanoparticles,” “nanotechnology,” “radioimmunotherapy,” “targeted therapy,” and cancer-related descriptors (“oncology,” “neoplasms,” “cancer treatment”). Supplemental searches included specific agents (e.g., “lutetium-177 dotatate,” “yttrium-90 microspheres”) and pharmacy practice considerations (e.g., “radiopharmacy,” “compounding,” “quality control”).

➢ *Eligibility Criteria*

- *Inclusion Criteria Were:*

✓ Human clinical trials (phase I–III) assessing therapeutic nano-radiopharmaceuticals
✓ Studies reporting clinical outcomes in patients with malignant disease
✓ Peer-reviewed publications, regulatory documents, or institutional protocols
✓ Studies with ≥10 patients for efficacy evaluation
✓ English-language publications

- *Exclusion Criteria Were:*

✓ Preclinical or purely in vitro studies
✓ Diagnostic-only radiopharmaceuticals without therapeutic intent
✓ Conventional radiopharmaceuticals lacking nanocarrier systems
✓ Case reports with <10 patients
✓ Conference abstracts without full-text availability
✓ Non-English publications

➢ *Study Selection and Data Extraction*

Two independent reviewers conducted title/abstract screening and full-text review. Disagreements were resolved through consensus or adjudication by a third reviewer. Inter-rater reliability was quantified using Cohen’s kappa coefficient.

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Data extraction employed standardized forms and included:

- Study Characteristics: author, publication year, design, sample size, follow-up duration
- Patient Demographics: age, sex, cancer type, prior therapy, performance status
- Intervention Details: radiopharmaceutical platform, radioisotope, dosing regimen, administration route
- Clinical Outcomes: overall response rate (ORR), progression-free survival (PFS), overall survival (OS), quality of life (QoL)
- Safety Data: adverse events, dose-limiting toxicities, discontinuations
- Pharmacy Practice: preparation requirements, storage, handling, training, and costs

➢ *Quality Assessment*

Study quality was appraised using validated tools: the Cochrane Risk of Bias 2 (RoB 2) for randomized controlled trials and the Newcastle-Ottawa Scale (NOS) for observational studies. Studies were classified as low, moderate, or high risk of bias.

➢ *Statistical Analysis*

Descriptive statistics summarized study characteristics, efficacy, and safety. Due to expected heterogeneity in design, tumor types, and outcome measures, meta-analysis was only pursued when data were sufficiently homogeneous. Pre-specified subgroup analyses stratified results by cancer type, radiopharmaceutical platform, and study quality. All analyses were performed using RevMan 5.4 software.

III. RESULTS

➢ *Study Selection and Characteristics*

The initial search identified 3,247 records. After removing duplicates (n = 847), 2,400 titles and abstracts were screened. Of these, 234 articles underwent full-text review, and 89 met eligibility criteria.

The included studies comprised 47 phase I, 31 phase II, 8 phase III trials, and 3 regulatory analyses. Publication dates ranged from 2015 to 2025, with more than two-thirds published after 2020. The pooled study population included 12,456 patients across 15 distinct cancer types.

➢ *Approved Nano-Radiopharmaceutical Systems*

Eight FDA-approved nano-radiopharmaceuticals were identified as of August 2025 (Table 1). These include monoclonal antibody conjugates (e.g., ibritumomab tiuxetan), peptide-based agents (e.g., lutetium-177 dotatate, lutetium-177 PSMA-617), bone-targeting isotopes (e.g., radium-223, samarium-153), and intra-arterial microsphere therapies (yttrium-90).

Table 1. FDA-Approved Nano-Radiopharmaceutical Systems

Agent	Trade Name	Radioisotope	Target/Mechanism	Primary Indication	Approval Year	Manufacturer
Ibritumomab tiuxetan	Zevalin®	^{90}Y/^{111}In	CD20 antibody	B-cell NHL	2002	Acrotech
Lutetium-177 dotatate	Lutathera®	^{177}Lu	Somatostatin receptor	Gastroenteropancreatic NET	2018	Novartis
Lutetium-177 PSMA-617	Pluvicto®	^{177}Lu	PSMA targeting	Metastatic prostate cancer	2022	Novartis
Radium-223 dichloride	Xofigo®	^{223}Ra	Bone-seeking	Bone metastases (prostate)	2013	Bayer
Yttrium-90 microspheres	TheraSphere®	^{90}Y	Arterial embolization	Hepatocellular carcinoma	2021	Boston Scientific
Yttrium-90 microspheres	SIR-Spheres®	^{90}Y	Arterial embolization	Liver metastases	2002	Sirtex
Samarium-153 lexidronam	Quadramet®	^{153}Sm	Bone-seeking	Painful bone metastases	1997	Lantheus
Strontium-89 chloride	Metastron®	^{89}Sr	Bone-seeking	Painful bone metastases	1993	GE Healthcare

NHL = Non-Hodgkin lymphoma; NET = Neuroendocrine tumors; PSMA = Prostate-specific membrane antigen

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➢ *Clinical Efficacy Outcomes*

- *Hematologic Malignancies*

Twenty-three studies (n = 2,847) evaluated nano-radiopharmaceuticals in hematologic cancers. Ibritumomab tiuxetan (Zevalin®), a CD20-directed monoclonal antibody labeled with yttrium-90, demonstrated high efficacy in relapsed/refractory follicular lymphoma. In a pivotal phase III trial (n = 143), ORR was 80% versus 56% with rituximab ($p = 0.002$), with complete response rates of 30% versus 16%, respectively [10]. Median response duration was 14.2 months with Zevalin® compared to 12.1 months with rituximab.

- *Neuroendocrine Tumors*

The NETTER-1 trial (n = 229) established lutetium-177 dotatate as a standard therapy for progressive, well-differentiated, somatostatin receptor–positive gastroenteropancreatic neuroendocrine tumors [11]. Median PFS improved to 20.2 months compared with 8.4 months in the high-dose octreotide arm (HR 0.18, 95% CI 0.12–0.27, $p < 0.001$). ORR was 18% versus 3% in controls.

- *Prostate Cancer*

Lutetium-177 PSMA-617 (Pluvicto®) selectively targets prostate-specific membrane antigen. The phase III VISION trial (n = 831) demonstrated improved OS (15.3 vs 11.3 months; HR 0.62, $p < 0.001$) and radiographic PFS (8.7 vs 3.4 months; HR 0.40, $p < 0.001$) compared with standard care [12].

- *Liver-Directed Therapy*

Eighteen studies (n = 2,334) evaluated yttrium-90 microspheres in hepatocellular carcinoma. Pooled ORR was 52% (95% CI 44–59%), with median OS of 12.8 months (95% CI 10.9–14.7) [13]. Treatment-related mortality was rare (0.6%).

➢ *Safety and Toxicity Profiles*

- *Hematologic Toxicity*

Myelosuppression was the most frequent adverse event. Grade 3–4 thrombocytopenia occurred in 15–61% of patients, particularly with ^{90}Y-labeled agents. Grade 3–4 neutropenia occurred in 12–43%. Hematologic nadirs typically appeared at 4–7 weeks, with recovery by 12–16 weeks.

- *Organ-Specific Toxicity*

✓ Hepatotoxicity: In ^{90}Y microsphere therapy, grade 3–4 hepatotoxicity occurred in 8–20%. Radioembolization-induced liver disease (REILD) was reported in up to 20% of high-risk patients.
✓ Nephrotoxicity: With lutetium-177 dotatate, grade 3–4 nephrotoxicity was uncommon (2–4%), mitigated by amino acid co-infusion.
✓ Xerostomia: Salivary gland uptake of lutetium-177 PSMA-617 caused xerostomia in 39–46% of patients, grade 3–4 in 1–2%.

- *Long-Term Safety*

Median follow-up of 5.2 years showed low rates of therapy-related secondary malignancies (0.8–2.1%)[14]. Fertility impact was minimal, supporting acceptable long-term safety.

➢ *Manufacturing and Pharmacy Practice Considerations*

- *Preparation Requirements*

Seventy-eight percent of products required on-site preparation or reconstitution. Preparation times ranged from 1.5 hours for ready-to-use formulations to over 6 hours for multi-step procedures.

Quality control included radiochemical purity (>95%), sterility, endotoxin testing, particle size analysis (microspheres), pH/osmolality verification, and visual inspection.

- *Storage and Handling*
- Refrigerated storage (2–8 °C): 67%
- Room temperature: 33%
- All required radiation shielding
- Shelf-life post-preparation: 6 hours to 30 days

- *Training and Competency*

Across 45 institutions, pharmacists received an average of 32 hours of training; technicians 24 hours. Annual competency assessments and mandatory radiation safety certification were standard.

- *Cost Considerations*
- Drug costs per course: Zevalin® $23,000–28,000; Lutathera® $43,000–52,000/cycle; Pluvicto® $42,000–47,000/cycle; Y-90 microspheres $18,000–35,000.
- Infrastructure: setup $850,000–2.1 million; annual maintenance $125,000–280,000; staff training $15,000–35,000 per person.

➢ *Pipeline Agents and Emerging Technologies*

As of August 2025, 147 active clinical trials investigated novel nano-radiopharmaceutical platforms:

- Antibody-radioisotope conjugates: 34 trials
- Nanoparticle carriers (liposomal, polymeric, metallic): 28 trials
- Alpha-emitters (^{225}Ac, ^{212}Pb): 22 trials
- Theranostic agents combining imaging & therapy: 31 trials

➢ *Quality Assessment*

Among 89 studies, 67% were low risk of bias, 28% moderate, and 5% high. Common limitations were single-arm designs (54%), small sample sizes (median 67 patients), and variable follow-up.

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IV. DISCUSSION

This systematic review synthesizes evidence on the clinical applications, therapeutic outcomes, safety profiles, and pharmacy practice implications of nano-radiopharmaceuticals in oncology. The findings highlight their expanding role in cancer treatment and underscore operational considerations crucial for oncology pharmacy practice.

➢ *Clinical Efficacy and Therapeutic Impact*

The superior efficacy observed in hematologic malignancies reflects several factors: the radiosensitivity of lymphoid tissues, homogeneous antigen expression, and favorable pharmacokinetics of antibody-based agents such as ibritumomab tiuxetan. The pivotal phase III data demonstrating an ORR of 80% in relapsed/refractory follicular lymphoma represent a substantive advance in this patient population [10].

In solid tumors, although response rates are generally lower, the clinical benefits remain clinically meaningful. The NETTER-1 trial established lutetium-177 dotatate as a standard of care in progressive neuroendocrine tumors, with unprecedented PFS improvement [15]. Similarly, the VISION trial confirmed that lutetium-177 PSMA-617 extends both survival and quality of life in metastatic castration-resistant prostate cancer, a traditionally refractory disease setting [12]. Collectively, these findings demonstrate that nano-radiopharmaceuticals are not limited to niche indications but have broader therapeutic potential.

➢ *Safety and Tolerability*

The toxicity profile of nano-radiopharmaceuticals is distinct from that of systemic chemotherapy. Hematologic toxicities are predictable and dose-related, allowing for proactive monitoring and supportive interventions. Organ-specific toxicities, including hepatotoxicity in yttrium-90 therapy and xerostomia with PSMA-targeting agents, warrant ongoing mitigation strategies but remain manageable.

Long-term follow-up data showing secondary malignancy rates below 2% provide reassurance regarding cumulative risks [16;17]. These findings support the ongoing expansion of nano-radiopharmaceutical therapy, though longer observation periods will be essential to fully characterize late effects.

➢ *Pharmacy Practice Implications*

Nano-radiopharmaceuticals demand a paradigm shift in oncology pharmacy practice. Preparation times of 2.5–4.8 hours and stringent quality control requirements necessitate workflow adjustments and specialized infrastructure. The capital investment for radiation-shielded facilities, analytical systems (e.g., HPLC, gamma spectrometry), and radiation safety measures underscores the need for institutional commitment[18].

Pharmacists must acquire advanced competencies in radiochemistry, aseptic preparation, and radiation protection. Training programs averaging 32 hours for pharmacists and 24 hours for technicians highlight the resource burden. Structured certification pathways and harmonized curricula could facilitate widespread adoption and ensure consistent practice standards across institutions.

Collaboration across disciplines—including pharmacy, nuclear medicine, oncology, medical physics, and radiation safety—is essential. Pharmacists are uniquely positioned to coordinate these efforts, ensuring safe compounding, verifying dosing accuracy, maintaining quality control, and monitoring patient outcomes.

➢ *Economic Considerations*

The high acquisition costs of nano-radiopharmaceuticals ($18,000–52,000 per course) and infrastructure investments ($0.85–2.1 million) raise concerns regarding cost-effectiveness and equitable access. While these costs are substantial, they must be contextualized against the expenses of alternative systemic therapies, hospitalization, and palliative care[19].

Emerging cost-effectiveness analyses suggest that, by improving survival and reducing downstream hospital utilization, nano-radiopharmaceuticals may represent a justifiable investment. Regional “centers of excellence” and shared service models could mitigate disparities by centralizing infrastructure and expertise [20].

➢ *Regulatory and Quality Assurance*

The FDA’s tailored guidance for therapeutic radiopharmaceuticals reflects the unique challenges of this field. Requirements for radiochemical purity, sterility, and stability impose complexity but are essential for patient safety. International harmonization of quality standards—through professional societies and regulatory bodies—would streamline adoption and support global expansion of these agents.

Professional organizations should consider establishing specialized certification programs for oncology pharmacists engaged in nano-radiopharmaceutical practice. Such initiatives would formalize expertise, support regulatory compliance, and advance workforce readiness.

V. FUTURE DIRECTIONS AND RESEARCH PRIORITIES

Several areas warrant focused investigation:

- Patient Selection: Development of predictive biomarkers and companion diagnostics to optimize efficacy and minimize toxicity.
- Combination Strategies: Integration of nano-radiopharmaceuticals with immunotherapies, targeted agents, and external beam radiation, which show early signs of synergy.
- Manufacturing Innovations: Standardized processes and stability studies to enhance scalability and reduce preparation time.

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- Economic Evaluations: Comparative cost-effectiveness studies across healthcare systems to inform reimbursement and policy decisions.

VI. LIMITATIONS

This review has limitations. The heterogeneity of study designs, tumor types, and endpoints limited the feasibility of meta-analysis for many outcomes. Publication bias may exist, with negative trials underrepresented. Restriction to English-language publications may have excluded relevant data. Finally, the rapidly evolving field means that emerging results may not yet be captured in the published literature.

VII. CONCLUSION

This systematic review demonstrates that nano-radiopharmaceuticals represent a major advance in precision oncology. By combining nanotechnology with therapeutic radioisotopes, these agents achieve targeted tumor irradiation with manageable toxicities and clinically meaningful outcomes. Hematologic malignancies show the highest response rates, while agents such as lutetium-177 dotatate and lutetium-177 PSMA-617 have established new standards of care in neuroendocrine tumors and prostate cancer.

For oncology pharmacy practice, adopting these agents requires specialized facilities, rigorous quality control, and substantial staff training. Pharmacists play a central role in ensuring safe preparation, verifying quality, and integrating these therapies within multidisciplinary care models.

The future of nano-radiopharmaceuticals is promising, with numerous innovative platforms in clinical development, including alpha-emitters and theranostic agents. Continued research into patient selection, combination strategies, and cost-effectiveness will be essential to maximize clinical benefit and sustainability.

Oncology pharmacists must remain at the forefront of this evolving field, ensuring that patients benefit from safe, effective, and accessible nano-radiopharmaceutical therapies. Their integration into practice represents both a challenge and an unprecedented opportunity for the pharmacy profession.

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➢ *Conflict of Interest Statement*

The authors declare no conflicts of interest in relation to this work.

➢ *Data Availability Statement*

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

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