REVIEW ARTICLE

Theranostics Driven by Nanotechnology: Novel Materials and Mechanistic Understandings in Precision Medicine

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Abstract

Theranostics-a novel conjunction of diagnostics and therapy in a single platform-is becoming a unique field of medicine that streamlines optimization of treatment for individual patients, known as precision medicine. The usual treatment methods generally involve diagnostic and therapeutic phases separately, thus delaying the disease observation and personalizing treatment choices. The revolution of nanotechnology in this field, modernized the nanomaterials by adhering multifunctional moieties to diagnose diseases, deliver drugs targeted to specific sites and monitor therapeutic response, is proving its versatility. Their large surface areas, as well as tunable dimensions, allow easy integration of imaging agents, drugs, and targeting molecules to optimize this versatility.

This review article will focus on the application of nanotechnology-driven theranostics, giving attention to new classes of nanomaterials and their impactful applications in the realm of precision medicine. Various types of nanomaterials, such as lipid-based, polymeric, inorganic and hybrid nanomaterials, will be discussed that enhance synergism between diagnostic and therapy modules. We will look at their fundamental mechanisms, which include targeting strategies, stimulus-responsive drug release, interactions with the biological system, and cellular internalization. We also look at recent advances in imaging-guided therapies, biosensing mechanisms and *in-vivo* monitoring of therapy.

Finally, we will focus on practical implementation of nanotechnology-based theranostics into clinics, such as nanotoxicity, distribution of nanoparticles into the body, challenges in production and regulatory guidelines. Lastly, future trends that can improve nanotheranostics, including biomimetic nanostructures, the use of AI in the design of nanomaterials and patient-specific theranostic agents, are critically reviewed.

Keywords: Nanotheranostics, Precision medicine, Nanoparticles, Targeted drug delivery, Bioimaging, Stimuli-responsive nanomaterials
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Introduction

Theranostics (Rx/Dx)-the portmanteau of therapeutic (Rx) and diagnostic procedures (Dx)-is an exciting developing area in the branch of nanomedicine, where diagnosis, targeted treatment and monitoring of therapeutic response are unified in one sophisticated platform to get more individualized and specific therapy for various pathological conditions[1]. The rise of theranostics is based on overcoming the limitations of conventional methods, which use separate diagnostic and therapeutic strategies. By unifying both aspects, it has been possible to detect and diagnose diseases at an early stage, select specific treatments and monitor patient responses throughout their therapy. Theranostics are also a great contribution to the field of precision medicine, a concept aimed at custom-tailoring medical treatments to an individual's specific medical history, genetic makeup, and biological characteristics. This enhances the patient's safety by decreasing the toxicity at off-target sites[2]. The application of nanotechnology to the development of theranostics is becoming more central to this pursuit[3].

Nanotechnology, which refers to manipulating matter on a nanoscale of 1-1000 nm, is integral to the development of theranostics. Nanoparticles offer uniqueness because of their versatile properties that are crucial for nanotheranostics. These include a smaller size that provides large surface-area-to-volume ratios and a high degree of surface tunability, allowing a variety of functional molecules, including drugs, imaging agents and targeting ligands, to be attached or incorporated into a single nanoscale construct. The nanoscale size of these particles helps in bypassing the reticuloendothelial uptake, renal clearance and blood vessel leakage. They are released only at target sites where there is blood vessel leakage[4]. Multifunctional nanotheranostic platforms that can both identify diseased tissues through imaging techniques and simultaneously deliver therapy are thus being explored[5]. Furthermore, nanotechnology-based theranostics are showing great promise in the development of new approaches for managing complex diseases such as cancer, cardiovascular diseases and neurological disorders.

Nanotheranostics may be understood as the creation

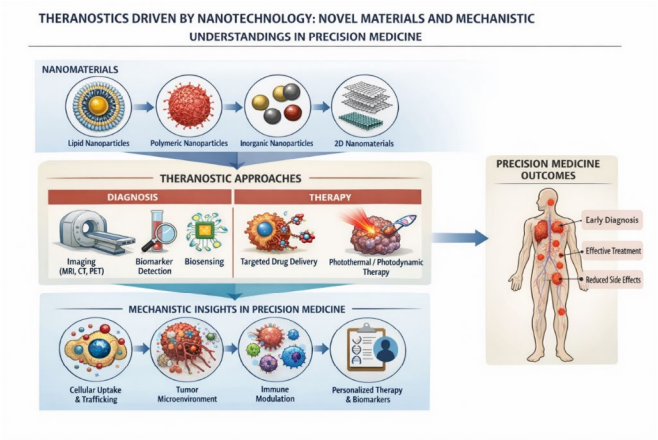

Figure 1: Graphical abstract: Nanotechnology in theranostics

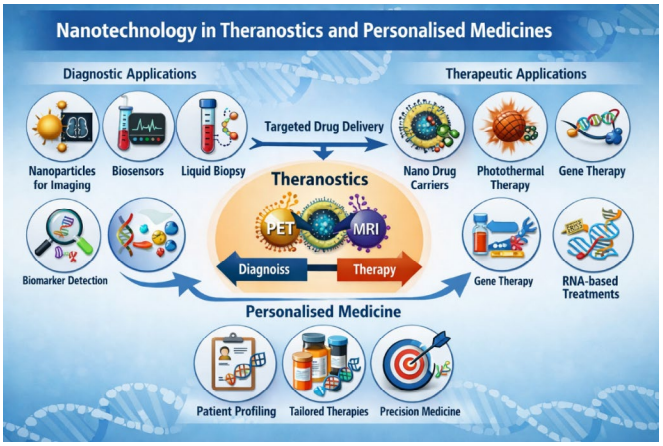

Figure 2: Nanotheranostics, a brief overview

of nanoparticles that simultaneously serve to both deliver a drug payload and act as a probe in an imaging modality. Nanotheranostics is to utilize and nurture nanomedicine strategies for proficient theranostics. The purpose is to diagnose and treat the diseases at their earliest stage, when the diseases are most likely curable or at least treatable. Several classes of nanostructures, such as polymer conjugations, polymeric nanocarriers, liposomes, micelles, dendrimers, metal nanoparticles, inorganic nanoparticles and carbon-based nanomaterials (carbon nanotubes) are being explored for their theranostic applications. These approaches can integrate imaging methods such as MRI, CT, PET and fluorescence imaging with drugs and gene delivery mechanisms. Theranostic platforms will enhance both diagnostic and therapeutic efficacy of treatments by sustained, controlled and targeted co-delivery of diagnostic and therapeutic agents for better theranostic effects and fewer side effects. This allows the physician to monitor the progression of the disease and the patient's response in real-time in a manner specific to that individual[6].

The ability to utilize some specific biological phenomenon, such as the enhanced permeability and retention (EPR) effect, is a significant aspect of nanotheranostics. This phenomenon helps direct the passive targeting of nanoparticles to specific sites, such as tumor sites. Targeting moieties (ligands) such as antibodies and peptides can also be attached to the nanoparticle surface; these specifically interact with cellular receptors and mediate nanoparticle uptake. Active targeting methods are beneficial, as they increase specificity and potentially reduce the harmful side effects of therapy. The targeting is further enhanced by integrating with stimulus-responsive delivery systems, thus simultaneously enhancing the ability to treat disease precisely[7].

With the advances in the field of nanoscience, the definition of theranostics was augmented, yielding multiple novel nanoplatforms which combine various therapeutic modalities such as gene therapy, photothermal therapy and chemotherapy with sophisticated imaging techniques. Such hybrid nanoplatforms can image tissues at the molecular level while continuously assessing therapeutic response, thereby offering unprecedented flexibility in therapy design. Nanotechnology-driven theranostics have therefore earned significant interest as an innovative strategy that promises to revolutionize personalized medical care. 'A graphical abstract illustrating nanotechnology in theranostics is shown in Figure 1.[8]

However, obstacles related to safety, systemic biodistribution, scaled production and regulatory concerns present substantial challenges in the transition of nanotheranostic technologies from research into clinical practice. Nonetheless, continued progress in nanoscience research has further enhanced the potential for these systems to provide highly efficient and less invasive diagnosis and therapy strategies. A brief idea about nanotheranostics is shown in Figure 2.

Evolution Of Theranostics And The Role Of Nanotechnology

Theranostics has rapidly evolved in recent years. From its humble beginnings rooted in traditional diagnostic and therapeutic techniques to state-of-the-art nanotech-driven approaches for diagnosing diseases, delivering targeted therapies and providing real-time feedback. The first generation of theranostics relies on radiopharmaceuticals to serve both diagnostic and therapeutic roles; these are typically used in cancer therapy and involve delivery of isotopes for both diagnosis and treatment (e.g.radioiodine used in the treatment of thyroid diseases has iodine-123 for imaging and iodine-131 for treatment)These methods, however, were plagued by lack of specificity and high systemic toxicities leading to its use in a limited number of clinical settings and thereby created a great need for targeted diagnostics and treatments that had higher therapeutic indices[9].

Nanoscience and material science have come a long way, and now it's possible to make nanoparticles that can be used for theranostics. Nanoparticles, due to their small size and versatility in their composition and surface features, are very useful for theranostics. A small unit of nanoparticles

can combine many functional parts; they are known to carry multiple payloads, such as drugs and imaging agents, which makes them good for theranostics. Nanoparticle-based theranostics have rapidly gained importance in oncological applications due to their ability to facilitate specific tumor identification and tailored treatments[10]. Theranostic nanoplatforms are broadening their functionalities beyond mere drug delivery, facilitating real-time diagnostics through imaging modalities such as MRI, CT, and fluorescence imaging.

A better understanding of the interaction between nanoparticles and biology, such as the EPR effect, which causes the accumulation of nanoparticles within tumors, is an important step for nanotheranostics. Through control over size, it is possible to passively target the tumor with nanoparticles carrying drugs, improving targeting. In addition to passive targeting strategies, active targeting using specific receptors overexpressed on the surface of cancer cells can also be implemented to achieve precise delivery of nanoparticles to the tumor and surrounding tissues. The active targeting strategy involves attaching specific ligands such as antibodies or aptamers to the surface of nanoparticles, enabling precise interaction and uptake by cancer cells overexpressing certain surface receptors. These active targeting strategies have significantly advanced therapeutic efficacy while reducing non-specific interactions with tissues throughout the body. Coupled with stimulus-responsive delivery, it is possible to deliver treatments that are finely tuned to the tumor microenvironment and only act at the designated location[7].

Correspondingly, advances in nanotechnology have facilitated the development of diverse nanomaterials with specific theranostic roles. A wide variety of nanomaterials were developed due to their versatility in theranostics, as discussed in earlier sections. For example, gold nanoparticles have emerged as efficient photothermal and imaging agents, whilst magnetic iron oxide nanoparticles are useful for MRI contrast imaging and targeted therapy delivery. Similarly, Quantum dots and mesoporous silica nanostructures are being investigated for their useful biomedical imaging characteristics and drug delivery applications. These nanoplatforms are able to work collectively, creating a highly sophisticated system for the monitoring and therapy of many types of cancer[11].

The advancement in biomedical sciences, molecular biology and computational technologies accelerated the progress and rapidity of theranostics development. Integration of nanotechnology with these fields of science allows the generation of new, smart theranostic systems with advanced features and personalized delivery approaches. For instance, in addition to all these advancements, the use of artificial intelligence has resulted in improved nanoparticle designs in terms of payload, size and targeting ability to match patient-specific profiles. Biomimetic nanomaterials, including exosome and cell-membrane coated nanoparticles, are being developed for increased compatibility, reduced immune rejection and enhanced targeting specificity[11].

Despite many hurdles such as safety concerns, biodistribution issues and challenges with large-scale manufacturing and regulatory approval for the transition of nanotheranostic technologies from lab scale to clinical application, research is in progress to optimize nanomedicine performance in terms of biocompatibility, drug loading capacity, targeting specificity and regulatory guidelines. Nanotechnology and theranostics will undoubtedly be important factors in the future advancement of many different targeted therapies and diagnostic techniques that rely on nanotechnology and theranostics.

Pharmacogenetics is a science that plays an important role in theranostics advancement. The DNA, RNA and protein sequence variations in different individuals and individual variations in therapeutic response for various treatment interventions will be dealt with pharmacogenetics with the aid of biomarkers. The pharmacogenetic application in theranostics will thus reduce time, thereby reducing cost and increasing the success rate of therapy[1,12].

Design Principles of Nanotheranostic Systems

A nanotheranostic platform typically includes:

Core Nanomaterial

Provides structural support and intrinsic imaging/therapeutic function.

- *Examples*
- Gold (plasmonic properties)
- Iron oxide (magnetic properties)
- Silica (porous drug loading)
- Polymeric matrices (controlled release)

Therapeutic Payload

- Chemotherapeutic drugs
- siRNA/mRNA
- CRISPR components
- Photosensitizers
- Radionuclides

Imaging Component

- Fluorophores
- MRI contrast agents
- PET/SPECT isotopes
- CT-active materials

Targeting Ligands

- Monoclonal antibodies
- Aptamers
- Peptides (e.g., RGD)
- Small molecules (e.g., folate)

Surface Modification

- PEGylation for stealth properties
- Charge optimization

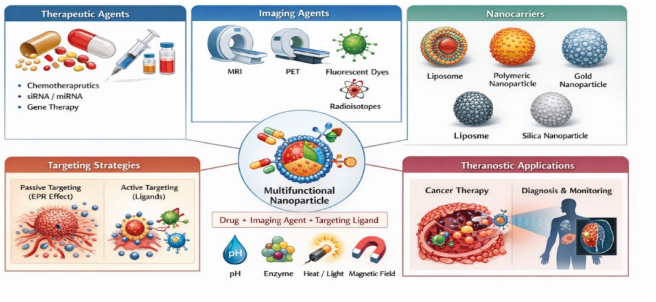

Figure 3: Components of nanotheranostics

- Stimuli-responsive coatings

The various components of nanotheranostics are shown in Figure 3.

Novel Nanomaterials For Theranostic Applications

Recent advances in nanoscience have given rise to a variety of novel nanoplatforms that are uniquely suited for combining diagnostic and therapeutic functions. The specific properties of the nanomaterials that make them suitable for theranostics include

- Nanoscale dimensions
- Large surface areas,
- Variable composition, i.e., tunable physicochemical properties
- Customizable surfaces and Multifunctional surface engineering capability
- Unique optical, magnetic, and electronic properties

By co-encapsulating imaging agents, therapeutics, and targeting components within the same nanosystem, these nanoplatforms promise effective disease visualization, precise delivery of therapeutic drugs, and monitoring of treatment effectiveness.

Recently, new categories of nanoplatforms, such as lipid-based nanomaterials (liposomes), polymeric nanocarriers, inorganic nanomaterials, iron-based nanoagents, nanocrystals and hybrid nanomaterials, have become important in theranostics.[11]

Due to their outstanding biocompatibility, bio-degradability and ability to incorporate a wide range of hydrophobic and hydrophilic drugs, lipid-based nanocarriers play a pivotal role among various theranostic nanoplatforms. The potential applications of liposomes, nanostructured lipid carriers (NLCs) and solid lipid nanoparticles (SLNs) for integrated therapy and imaging, especially in cancer, are being extensively researched. The therapeutic performance of therapeutic agents can be visualized by the image-guided delivery of liposomes as they carry both imaging probes (such as fluorescent tags or magnetic nanoparticles) and drugs within a single entity. By modifying the surface of nanocarriers with specific targeting ligands, the accumulation of theranostic agents at disease sites can be made possible and thus reducing their distribution throughout the rest of the body. This further reduces side effects of therapy. Multiple clinically approved liposome-based drugs demonstrate the success and versatility of this nanoplatform in treating disease, which continues to fuel research efforts in this area.[13]

Polymeric nanocarriers represent another major class of nanomaterials that are under intense investigation for their theranostic abilities. These structures are prepared using biodegradable polymers such as poly (lactic-co-glycolic acid) (PLGA), polyethylene glycol (PEG) and polycaprolactone (PCL), and allow excellent control over their drug loading capacity, release rate, and surface features. Polymeric nanocarriers can be designed to be stimuli-responsive and release therapeutic agents based on localized stimuli such as variations in pH or certain enzyme activities that may be encountered at disease sites[10]. Furthermore, they can be conveniently functionalized with both therapeutic and imaging agents to achieve co-delivery of diagnostics and therapeutics, allowing comprehensive real-time monitoring of therapy. The use of dual agents, i.e., dendrimers and polymeric micelles, can be used in cancer imaging and imaging-guided therapy approaches; thus, they can provide highly effective patient-specific treatments.

Researchers are getting more interested in using inorganic nanoparticles for theranostics, which is a way to diagnose and treat diseases at the same time. This is because these tiny particles have special magnetic, optical, and electronic properties that make them really useful. For example, some nanoparticles, like gold, can create strong surface plasmon resonances, which means they can be used to make images of the body, help with therapy, and diagnose diseases. They can even make images of specific tissues clearer when used with other imaging agents. When gold nanoparticles are exposed to light, they can also generate a lot of heat in a small area, which is called photothermal therapy. This makes them really good at treating certain types of tumors, especially when used with other treatments. Another type of nanoparticle, called SPIONs, can be used as contrast agents for MRI scans, which help doctors see inside the body more clearly. But now, scientists have found a way to modify these particles so they can also deliver drugs directly to the right spot in the body. Other types of nanoparticles, like quantum dots and mesoporous silica nanoparticles, are really good at making images of the body and have special properties that make them glow. They also have a big surface area and a porous structure, which means they can be loaded with drugs and used for both imaging and delivering therapy at the same time. This is a really exciting area of research because it could lead to new and better ways to diagnose and treat diseases. By using these nanoparticles, doctors may be able to target diseases more precisely and effectively, which could improve patient outcomes and save lives[9].

Hybrid nanocarriers provide additional functionality by integrating organic and inorganic moieties in one structure and offer many advantages, such as combining the benefits of organic polymers and inorganic nanomaterials. Combining polymeric or lipid-based platforms with inorganic nanoparticles is beneficial; for instance, SPIONs coated with

lipids reduce interaction with other biomolecules in the body, thereby allowing enhanced delivery to target cells and improved imaging performance. The other examples include metal-containing polymer nanohybrids and metal-coated silica nanoparticles, where the synergy of organic polymer and inorganic particle results in versatile drug loading capacity, controllable delivery and effective bioimaging capabilities. Other hybrid nanomaterials, such as metal-organic frameworks (MOFs) are being developed as novel systems that combine high capacity drug loading and stimuli-responsive delivery with integrated imaging functionalities[14].

Various types of nanomaterials and their theranostic properties were tabulated in Table 1.

Mechanistic Insights In Nanotheranostics

The thorough knowledge of the mechanism of action plays a crucial role in the effective design of nanotheranostic systems to achieve accuracy in diagnosis, therapeutic efficiency and translational medical application. In order to minimize systemic toxicities and other side effects and to achieve targeted delivery to a specific site, the mechanisms involving targeting strategies, interactions with the biological systems, stimulus-responsive delivery and cellular uptake are critical. These approaches allow physicians to improve both diagnostic specificity and the success rate of therapies[14].

The main driving principle behind passive targeting in nanotheranostics revolves around the EPR effect. The tumor tissues express aberrant microvascular structures and deficient lymphatic drainage, allowing optimally sized particles (ranging from 10–200 nm) to selectively accumulate within diseased locations due to slow clearance of the particles from this site. Because of this, tiny particles (between 10–200 nm) can accumulate in the diseased area. They do this because they are not cleared from the site quickly. The EPR effect is a key part of cancer theranostics. It helps get more of the therapeutic and diagnostic agents to the specific area, and not to healthy parts of the body. This makes the treatment more effective [15]. However, effectiveness can vary based on numerous factors, such as the type and size of the tumor and physiological variables, making a singular reliance on the EPR effect alone insufficient; additional targeted therapies are being designed in conjunction with these approaches.

Table 1: Types of nanomaterials and their theranostic properties

Nanomaterial type	*Key characteristics*	*Diagnostic function*	*Therapeutic function*	*Advantages*	*Representative references*
Liposomes	Phospholipid bilayer vesicles capable of encapsulating hydrophilic and hydrophobic drugs	Fluorescence imaging, and MRI when loaded with contrast agents	Chemotherapy delivery, gene delivery	High biocompatibility, clinical approval for several formulations	Bozzuto & Molinari, 2015 [13]
Polymeric Nanoparticles	Biodegradable polymers such as PLGA, PEG, PCL	Fluorescence imaging, MRI when conjugated with probes	Controlled drug delivery, gene therapy	Tunable drug release and surface functionalization	Mura *et al*., 2013[10]
Dendrimers	Highly branched synthetic macromolecules	Fluorescent imaging and targeted imaging	Targeted drug delivery and gene therapy	High drug loading capacity and multivalent surface modification	Janib *et al*., 2010[11]
Gold nanoparticles	Noble metal nanoparticles with strong plasmonic properties	CT imaging, photoacoustic imaging	Photothermal therapy and targeted drug delivery	Excellent optical properties and easy surface modification	Shi *et al*., 2017[14]
Iron oxide nanoparticles	Superparamagnetic nanoparticles	MRI contrast agents	Magnetic hyperthermia and drug delivery	Strong magnetic properties and imaging capabilities	Kelkar & Reineke, 2011[9]
Quantum dots	Semiconductor nanocrystals with tunable fluorescence	High-resolution fluorescence imaging	Drug delivery and photodynamic therapy	High photostability and tunable emission spectra	Fan *et al*., 2014[6]
Mesoporous silica nanoparticles	Nanoparticles with large pore structures	Fluorescence and multimodal imaging	Controlled drug release and photothermal therapy	High surface area and drug loading capacity	Muthu *et al*., 2014[7]
Metal–organic frameworks (MOFs)	Hybrid porous crystalline nanostructures	Multimodal imaging (MRI/fluorescence)	Controlled drug release and catalytic therapy	High porosity and multifunctional design	Shi *et al*., 2017[14]

Active targeting is another strategy used to improve specificity in nanotheranostic systems. By conjugating specific biomolecules that recognize tumor-associated receptors or biomarkers onto the nanoparticle surface, active targeting ensures that only cancerous tissues that express high levels of these markers are loaded with targeted therapy. Examples include monoclonal antibodies and peptide ligands. Folic acid can also be conjugated, as it is highly expressed by numerous types of tumors. When these receptor-binding ligands interact with tumor-associated cell surface receptors, they trigger their endocytosis via the process of receptor-mediated endocytosis and facilitate the transport of their therapeutic load to the interior of the cell. This leads to reduced side effects associated with these systems since interactions outside of the intended target are limited[7].

Stimuli-responsive delivery is a key component of theranostics in which drugs are released from nanoparticles when certain stimuli present at the disease site are encountered. There are many forms of stimuli that can cause drug release; internal stimuli can include variations in pH, redox potential, or enzyme levels. Tumor sites tend to have more acidic microenvironments and are also prone to having a higher concentration of reactive species compared to healthy tissues. Therefore, nanoparticles responsive to pH changes or higher redox potentials would be highly beneficial to patients suffering from cancer, since these features are amplified at tumor sites as opposed to elsewhere in the body[10]. External stimuli such as light and ultrasound can also be employed in controlled therapeutic delivery and integrated with imaging modalities for superior imaging-guided therapy.

The interaction of nanoparticles with biology is critical for designing nanotheranostic platforms that can be delivered systemically with adequate stability and circulating time. Upon injection, nanoparticles interact with plasma proteins, creating what is called the "protein corona". This protein layer can either facilitate or hinder targeted delivery. The protein corona could mediate cellular recognition, which may activate the clearance of nanoparticles by immune cells. Conversely, it may also assist with targeting and improve delivery to the desired cellular components. Therefore, understanding how surface characteristics influence the protein corona and thereby the behavior of nanoparticles within the human body is a crucial design feature [16].

The cellular uptake pathway utilized by nanotheranostic systems will influence the time required and the effectiveness with which drugs are released. Nanoparticles that are endocytosed are transported through endosomes, which fuse with lysosomes, which can contain enzymes to break down the nanoparticle or its load. Efficient endosomal escape is necessary to avoid degradation by the lysosome. The proton sponge effect and the use of membrane-disrupting peptides can facilitate the delivery of contents to the cell cytosol. Imaging and real-time analysis of nanoparticle location within the body can greatly contribute to our understanding of how to improve delivery into the cellular interior and ultimately the effect these nanoparticles will have on target cells[11]. The mechanistic insights of nanotheranostics were represented in Figure 4.

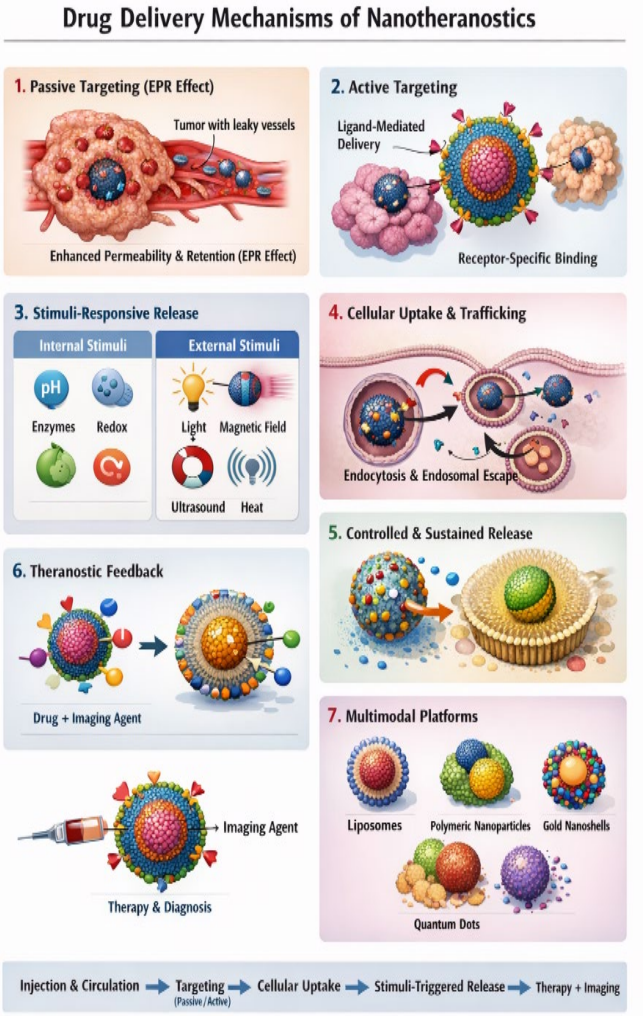

Figure 4: Mechanistic insights in nanotheranostics

Diagnostic Modalities Enabled By Nanotheranostics

Nanotheranostic systems, developed by integrating nanomedicine and imaging technologies, have expanded the dimensions of diagnosis and disease monitoring. Such sophisticated diagnostic methods offer sensitive, time-dependent, and multi-modal detection of abnormalities at various disease sites. They permit both accurate imaging of diseased locations, diagnosis of ailments and monitoring of therapeutic success at one single integrated nanosystem platform. Unique optical, magnetic, and electronic properties presented by different nanocarriers further refine diagnostic visualization and enhance accumulation at specific tissues of concern, thereby enabling more targeted diagnostic applications [11].

Magnetic resonance imaging (MRI) is one of the established imaging techniques that can be employed in theranostics. Superparamagnetic iron oxide nanoparticles (SPIONs) have attracted significant attention as contrast agents for enhancing the signal-to-noise ratio (SNR) in MRI, thereby producing high-resolution images. The capacity of SPIONs to carry therapeutic agents with targeting ligands enables both simultaneous targeted delivery of drugs and imaging feedback about nanoparticle accumulation within tissues. MRI-guided nanotheranostics are also found promising for early tumor imaging and localization and accurate treatment planning in oncology. MRI's high spatial resolution allows deep tissue penetration, thus enabling visualization of the behavior of nanocarriers deep within the human organs and tumors[9].

Computed tomography (CT) imaging is another widely accepted imaging modality that allows for high-resolution imaging through X-ray attenuation. Metallic nanocarriers such as gold nanoparticles (GNPs) are popular CT contrast agents because of their high atomic numbers. They are currently being explored for imaging and photothermal therapy of cancer tissues. GNPs have demonstrated excellent targeting ability and higher contrast performance over conventional iodine-based contrast agents in imaging techniques. The application of GNPs as dual targeting and imaging agents has significant promise in both diagnosis and therapy of complex pathologies[14].

Fluorescence imaging represents another significant diagnostic approach that can be used in nanotheranostics. Nanoparticles such as quantum dots (QDs), carbon dots (CDs) and other fluorescent nanomaterials are preferred for bioimaging as they demonstrate enhanced fluorescence quantum yield, photostability and are tunable, emitting different wavelengths of light, allowing for highly sensitive visualization of biological biomarkers and real-time monitoring of cellular activity. They are widely used for molecular imaging and for monitoring cellular-level tracking for diagnostics and therapy. Certain fluorescent nanomaterials have also been used as highly sensitive and specific biosensors to detect a multitude of disease-linked biomarkers with increased sensitivity over traditional assays[6].

Multimodal imaging represents the combination of two or more imaging techniques in a single nanoparticle-based nanotheranostic system. This strategy may compensate for individual method limitations, thus resulting in the highest specificity. For instance, nanoparticles may be engineered to exhibit both MRI and fluorescence capabilities or to include X-ray/CT imaging in the form of GNPs integrated within different modalities to simultaneously provide high-resolution images alongside sensitive molecular detection for highly informative diagnostic applications. This allows for detailed analysis of anatomy and cell surface receptor expression levels, and dynamic monitoring of treatment responses to improve treatment effectiveness and minimize non-specific interaction[7].

In addition to improved imaging capabilities, theranostics is also pushing the development of a wide variety of new biosensors capable of identifying disease-associated biomarkers such as DNA/RNA sequences, proteins, or circulating tumor cells at very low concentrations. Such nanoparticle-based sensors are useful for early diagnosis of diseases, as well as non-invasive treatment monitoring of conditions such as cancer, cardiovascular diseases, and neurodegenerative disorders. Advances in liquid biopsy utilizing these nanoparticles allow for precise analysis of biological samples without the need for the sample to be collected invasively from tissues[14].

Lastly, monitoring of treatment response using real-time imaging feedback is critical to personalize therapy selection. Nanotheranostic agents, which inherently possess both imaging and therapeutic abilities, will enable physicians to track the progression of their therapy by imaging the tumor in real time to confirm that the target is indeed being treated by the therapy, as well as how well they are reacting to it. Such information enables physicians to optimize therapeutic dosages for each individual and fine-tune treatments as needed, allowing a level of personalized treatment hitherto unimaginable in medicine[11].

Therapeutic Applications Of Nanotheranostics

Nanotheranostic systems are being rapidly developed to address diverse and complex diseases by synergistically integrating therapeutic delivery with diagnostic imaging and monitoring strategies. The multipurpose functionalities displayed by nanocarriers allow the integrated approach of diagnostics, imaging, drug delivery and therapy monitoring, facilitating individualized and more effective treatment strategies. Theranostics improves targeting efficiencies, therapeutic effectiveness and limits systemic toxicity for prevalent diseases such as cancer, cardiovascular diseases, neurodegenerative diseases, infectious diseases, etc. It enables physicians to visualize drug distributions in real time, monitor treatment progress and refine therapy depending on patient needs[14].

The real-time diagnosis and localized therapy of nanotheranostics have enabled them to attain immense traction in cancer treatment. Theranostic nano-systems can deliver anti-cancer agents directly to tumor sites and improve diagnostic efficiency of ongoing therapy by continuously imaging nanoparticle distribution and tumor response in real time. Diverse types of nanocarriers like SPIONs, gold nanoparticles, polymeric carriers and liposomes have been developed as dual target imaging and drug delivery platforms that are able to carry drugs like chemotherapeutics and integrate with imaging techniques such as MRI, CT and fluorescent imaging. Photothermal and photodynamic therapies, two new treatment approaches based on SPIONs, are being studied; these novel strategies exploit particular light-based energy to directly target cancer cells without affecting normal tissue. These innovative imaging-guided approaches allow effective and personalized treatments

Table 2: Various therapeutic applications of theranostics

Application area	*Type of nanotheranostic system*	*Mechanism of action*	*Therapeutic benefit*	*Representative nanomaterials*	*Key outcomes / notes*
Cancer Therapy (General Oncology)	Targeted theranostic nanoparticles	Simultaneous imaging + drug delivery via passive (EPR effect) & active targeting	Reduced systemic toxicity; enhanced drug accumulation in tumors	Liposomes, polymeric NPs, dendrimers, gold NPs	Improves therapeutic index and enables personalized oncology [5,17]
Image-Guided Drug Delivery	Multifunctional imaging nanoprobes	Combines MRI/CT/ fluorescence imaging with therapeutic payloads	Real-time tracking of drug distribution	Iron oxide NPs, quantum dots, upconversion NPs	Enables precision medicine and monitoring of treatment response [5]
Photothermal Therapy (PTT)	Light-responsive nanoparticles	Convert NIR light into heat to ablate tumor cells	Minimally invasive tumor destruction	Gold nanorods, carbon nanotubes	Selective tumor ablation with minimal damage to healthy tissues [5]
Photodynamic Therapy (PDT)	Photosensitizer-loaded nanocarriers	ROS generation upon light activation	Induces apoptosis in cancer cells	Porphyrin-based NPs, silica NPs	Effective in combination therapies for solid tumors [5]
Brain Tumor Therapy	BBB-penetrating nanocarriers	Cross blood–brain barrier and deliver drugs selectively	Improved drug bioavailability in CNS	Polymeric NPs, lipid-based NPs	Overcomes major limitation of conventional chemotherapy [18]
Colorectal Cancer Therapy	Stimuli-responsive nanotheranostics	pH/enzyme-triggered drug release in tumor microenvironment	Site-specific delivery; reduced side effects	Mesoporous silica NPs, PEGylated NPs	Enhanced tumor inhibition and controlled release [19]
Magnetic Hyperthermia Therapy	Magnetic theranostic nanoparticles	Heat generation under alternating magnetic field	Tumor cell destruction + imaging	Iron oxide nanoparticles	Dual role in MRI imaging and therapy [20]
Antimicrobial & Infectious Diseases	Theranostic nanocarriers for pathogens	Targeted drug delivery + diagnostic detection	Improved treatment of resistant infections	Silver NPs, polymeric nanocarriers	Effective against intracellular pathogens and AMR [21]
Inflammatory Disorders	Smart nanotheranostics	Target inflamed tissues using biomarkers	Reduced inflammation and side effects	Lipid nanoparticles, polymeric micelles	Controlled drug release at inflammation sites [21]
Gene Therapy / RNA Delivery	Nucleic acid-loaded nanocarriers	Deliver siRNA/mRNA with imaging capability	Gene silencing + disease monitoring	Lipid NPs, exosomes	Emerging approach in precision medicine
Cardiovascular Diseases	Targeted vascular nanotheranostics	Imaging + therapy of atherosclerotic plaques	Early detection and treatment	Gold NPs, magnetic NPs	Enables early-stage intervention
Multimodal Combination Therapy	Hybrid theranostic systems	Combine chemo + PTT + PDT + imaging	Synergistic therapeutic effects	Hybrid nanocomposites	Overcomes drug resistance and tumor heterogeneity [22]
Preclinical Models (Zebrafish, etc.)	*In-vivo* nanotheranostic platforms	Study biodistribution, toxicity, and efficacy	Accelerates translational research	Liposomes, micelles, exosomes	Cost-effective and high-throughput validation models [23]

with greater tumor targeting and minimal damage to healthy tissues[6].

Apart from cancer, nanotheranostics have potential applications for treating cardiovascular diseases that contribute largely to global morbidity and mortality. Researchers are using nanoparticles for identifying and targeting problem areas such as blood clots, inflammation and arterial stenosis. SPIONs used for MRI can help image plaques that form on arterial walls, and can also be modified to deliver therapy for treating conditions like stenosis, stroke and myocardial infarction. Active targeting of nanocarriers to such specific areas not only helps detect diseases earlier, but also improves the effectiveness of treatments in cardiovascular medicine. Nanotheranostic platforms further help monitor how well treatment is proceeding[11].

Targeted diagnosis and therapy are very important for neurodegenerative diseases such as Parkinson's and Alzheimer's disease, as it can be challenging to cross the blood-brain barrier (BBB) and deliver therapy to targeted brain tissues. This challenge is efficiently tackled by engineered nanoparticles through their effective delivery of imaging agents or drugs through the BBB to the desired targets. They can be utilized as both diagnostic agents and therapeutics for neurological conditions by tracking

how well therapies are distributed across the BBB. This will hopefully contribute to early diagnosis and treatments for neurodegenerative diseases[10].

Applications of nanotheranostics in infectious diseases are also being investigated, for imaging of pathogens, targeted therapy and monitoring of treatment success. Nanoparticles such as QDs and gold nanoparticles have demonstrated the capacity to be used as highly sensitive biosensors for the diagnosis of various bacterial and viral infections. By limiting degradation, delivering medications to affected locations, and enhancing therapeutic indices, nanoparticle-based nanocarriers contribute to increased drug efficacy in antimicrobial therapies. These techniques have a big impact on antibiotic resistance and the diagnosis and treatment of newly developing diseases[7].

Further, nanotheranostics systems hold promise for gene therapy, by transporting genetic material such as plasmids and small interfering RNAs (siRNAs) to target cells and, at the same time, imaging the cells to assess the delivery of these treatments. Nanotheranostic devices are also being developed for immunotherapy for cancer treatment, such as the administration of cancer vaccines and checkpoint inhibitors, coupled with real-time imaging to evaluate efficacy and refine treatments accordingly[14].

The therapeutic applications of various nanotheranostics and recent studies on theranostics were summarized with brief descriptions in Tables 2, 3 & 4

Clinical Translation And Current Clinical Trials

Although great progress has been made in nanotheranostics in laboratory settings, the progression from the lab to the clinic is complicated and often a daunting prospect. In addition to proof of efficacy and diagnostic performance, efficient clinical translation requires data demonstrating satisfactory safety profiles, reproducibility, scalability and the fulfillment of regulatory requirements. Over the past two decades, several nanomedicine formulations have progressed into clinical trials, some have been approved for therapy or diagnosis, suggesting that nanotechnology-enhanced theranostics could be a reality in precision medicine, but experimental systems are still at the nascent stage of development[14].

One of the first to reach the clinic was liposome-based drug delivery systems, which had increased pharmacokinetics and improved toxicity compared to conventional delivery formulations. Liposomal formulations like liposomal doxorubicin are common in treating cancer because they tend to localize in the tumor sites through the EPR effect, although they lack the dual functionality for diagnosis and therapy, their successful application paves the way for the future of advanced nanomedicine formulations. This success has led to the design of more advanced systems that could offer both imaging and therapeutic capabilities in one nanoparticle[13].

Iron oxide nanoparticles have gained prominence as MRI contrast agents for use in a number of clinical applications. SPIONs (superparamagnetic iron oxide nanoparticles) possess good compatibility and are excellent imaging agents that can be used to visualize tumors, examine lymph nodes, or illustrate inflammatory areas. SPIONs have also been investigated for combined diagnosis and therapeutic use, including targeted drug delivery and magnetic hyperthermia. Clinical trials using iron oxide nanoparticles have revealed a wealth of information regarding distribution, pharmacokinetics and safety of these nanoparticles in humans[9].

The current clinical landscape for nanotheranostics also includes the investigation of gold nanoparticles. Due to their unique optical properties and biocompatibility, they have sparked significant interest, and trials are ongoing for photothermal therapy image guided therapies. Gold nanoparticle-based nanostructures for NIR photothermal therapy, for example, have been applied to assess the aggressiveness of solid tumors. These are delivered to the tumor tissue, and upon application of NIR radiation, they cause local hyperthermia and kill cancer cells. These strategies demonstrate the potential within nanotheranostics for combining imaging and therapy in the clinic[24].

Recent work combining advanced nanotechnology with molecular imaging and targeted therapies has produced multifunctional nanotheranostic platforms currently in clinical development. These usually have a diagnostic imaging moiety such as radionuclide, fluorescent reporter, MRI contrast agent, or the combined application of targeting molecules and therapeutic agents. The nanoparticle platforms are under clinical evaluation for tumor imaging, targeted delivery of therapy and image-guided therapeutics. Concurrently, research into diagnostics and biomarker discovery has also led to more targeted theranostics that are able to individualize therapy for better clinical outcomes[11].

Although promising results have been obtained for the application of nanotheranostics in a clinical environment, there are still a range of challenges to overcome. A significant hurdle is that of nanotoxicity and long-term safety because of the unique interactions between nanoparticles and the body's complex biology. Build-up of nanoparticles within target organs like the liver or spleen might lead to chronic toxicity, as might immune system complications that require thorough research before clinical approval can be obtained. Furthermore, the manufacture of such complex nanomaterials needs to be scalable, and problems with size and chemical or composition variations will impact their ability to deliver effective treatments[10].

The regulatory view of the clinical translation of nanotheranostics solutions must also be considered. As they usually incorporate both diagnostic and therapeutic components, they are often subject to multi-faceted regulation requirements requiring a comprehensive evaluation of both. Several parameters will need to be considered during regulatory assessment, including stability, pharmacokinetics, toxicity and long-term safety before the products can be approved for marketing. Therefore, inter-disciplinary collaboration between scientists, clinicians,

Table 3: Recent studies on nanotheranostics

Nanomaterial	*Disease target*	*Diagnostic modality*	*Therapeutic strategy*	*Key findings*
Polymeric nanoparticles	Cancer	MRI, fluorescence imaging	Targeted chemotherapy	Demonstrated simultaneous tumor imaging and drug delivery [11]
Quantum dots	Cancer	Fluorescence imaging	Photodynamic therapy	Enabled real-time tumor detection and ROS-mediated tumor destruction [6]
Stimuli-responsive polymeric nanoparticles	Tumors	Fluorescence imaging	Controlled drug release	pH-responsive drug delivery improved therapeutic specificity [10]
Gold nanoparticles	Solid tumors	Photoacoustic and CT imaging	Photothermal therapy	Effective tumor ablation using near-infrared laser activation [14]
Biomimetic nanoparticles	Cancer	Fluorescence and MRI	Targeted drug delivery	Improved immune evasion and tumor targeting [6]
AI-assisted nanoparticle design	Multiple diseases	Multimodal imaging	Personalized therapy	AI optimization improved nanoparticle targeting efficiency [25]

Table 4: Clinical trials and translational status of nanotheranostic systems

Nanoparticle system	*Application*	*Clinical status*	*Diagnostic modality*	*Therapeutic function*	*Key notes*
Liposomal Doxorubicin (Doxil)	Cancer therapy	FDA approved	Indirect imaging capability	Chemotherapy	Improved drug pharmacokinetics and reduced cardiotoxicity
Iron Oxide Nanoparticles (Ferumoxytol)	Tumor and vascular imaging	FDA approved	MRI contrast agent	Potential drug delivery carrier	Widely used for MRI-based diagnostics
Gold Nanoshells	Solid tumors	Clinical trials	Photoacoustic imaging	Photothermal therapy	NIR-triggered tumor ablation
Nanoparticle Albumin-bound Paclitaxel (Abraxane)	Breast and pancreatic cancer	FDA approved	Imaging-guided therapy research	Chemotherapy	Improved drug solubility and tumor targeting
Hafnium Oxide Nanoparticles (NBTXR3)	Radiotherapy enhancement	Phase II/III trials	CT imaging	Radiation therapy enhancement	Enhances tumor sensitivity to radiation
SPION-based nanocarriers	Cancer imaging	Clinical research stage	MRI	Magnetic hyperthermia and drug delivery	Investigated for imaging-guided therapy

regulatory bodies and the pharmaceutical industry is essential to meet this challenge[14].

Nanoparticle Theranostics: Challenges And Limits

The realm of nanotheranostics has witnessed an impressive growth trajectory, yet numerous scientific, technical and regulatory challenges hinder the widespread translation of the innovative technologies to the clinical setting. Although nanotheranostics systems have demonstrated tremendous promise in integrated therapeutics and diagnostics within a nano-scale, intricate nanostructures and their interaction pose a number of challenges that should be addressed prior to clinical use. Nanotoxicity and long-term safety, biodistribution and interactions with the biological systems, scale-up of production processes, as well as gaining regulatory approval, are a few of the factors that need to be controlled prior to the implementation of nanotheranostics for precision medicine [14].

One of the main concerns in nanotheranostics is nanotoxicity and long-term safety. Nanoparticles interact with biological systems in a complex and unpredictable way due to their small size and high surface area-to-volume ratio. When given *in-vivo*, some nanomaterials may cause inflammation, oxidative stress, or an immunological reaction. After systemic administration, some inorganic nanoparticles can accumulate in important organs like the spleen, liver, and kidney, which can affect safety and cause long-term health problems. In contrast, surface modifications of nanoparticles like PEGylation have demonstrated enhanced stability and immune system evasion. Before long-term toxicity studies and biodegradability assessments are commonly used in clinical settings, they must be thoroughly examined[16].

Biodistribution and Pharmacokinetics in nanotheranostics present another major issue with nanoparticles' interaction with biological systems. One prerequisite for nanotheranostic systems is their ability to target specific diseased tissues and

escape uptake by the mononuclear phagocytic system. Upon injection, they are rapidly sequestered by macrophages in the spleen and liver, resulting in a decrease in the circulating time and localization in diseased tissues. Moreover, variations in tumor characteristics, vascular permeability and microenvironment influence the targeting efficiency with respect to the EPR effect, thus resulting in inconsistent therapeutic outcomes and slow advancement toward clinical utility[15].

Formation of protein corona on the surface of the nanoparticles is a major concern with the implementation of nanotheranostics. Following administration into biological fluid, plasma proteins are immediately adsorbed to nanoparticle surfaces, leading to the formation of a protein layer which affects stability, cellular uptake, targeting efficiency and immune interaction. In some instances, it may even obscure the targeting ligand attached to the surface of the nanoparticle, resulting in decreased targeted delivery. Understanding the process of protein corona formation is therefore crucial to optimizing the performance of the nanotheranostic systems with appropriate surface engineering strategies[16].

Beyond the biological challenges, the scalability of manufacturing and reproducibility pose a problem for the development of nanotheranostic systems. Numerous nanomaterials are synthesized through multi-step procedures, which lead to difficulty in maintaining batch-to-batch consistency. Variations in parameters such as nanoparticle size, shape, surface and loading characteristics will affect the biological impact and therapeutic results. The consistency in production quality will be an imperative parameter to be ensured for regulatory approval and subsequent commercialization of nanotheranostic products. Furthermore, the high cost associated with the production and characterization of nanomaterials may limit their availability and accessibility for clinical applications[24].

The regulatory perspective plays a significant role in the transition of nanotheranostic technology to clinical applications. As they comprise both imaging and therapeutic modalities, these platforms are frequently categorised according to stringent guidelines, with a need to investigate both aspects critically for their safety and therapeutic value. These regulatory bodies evaluate factors such as pharmacokinetics, toxicology, imaging outcomes and therapeutic results. The lack of universally standardized regulations for nanomedicine causes a delay in approval and thus a slow translation of promising nanotheranostics. Establishing clear regulatory pathways is a must to pave the way for the clinical translation of nanotheranostics[14].

Disease microenvironments often exhibit heterogeneity with regard to cancer diagnostics and therapeutics, thus posing a barrier to nanotheranostics applications. The variety of characteristics of the tumor tissues, such as vascular structures, microenvironment conditions, and interstitial pressure, will affect the efficiency of nanoparticle accumulation within the tumor tissues, meaning a nanotheranostic system that works well in the lab setting may not provide the desired results in a clinical scenario. Personalized nanomedicine is therefore needed to cater to specific disease characteristics[10].

In conclusion, the promising future of nanotheranostics in advancing precision medicine will be reliant on the efficient development of nanotechnology beyond these challenges and limitations. The success of these multi-modal nano-systems is linked with the optimization of nanoparticle safety, targeted delivery, large-scale production processes, and relevant regulatory approvals. An interdisciplinary approach with further innovation in nanobiomaterials and a better understanding of biological interactions and the development of improved regulatory strategies will facilitate the transformation of nanotheranostics to potent clinical tools.

Future Directions And Advancements In Nanotheranostics

With new research and innovations in nanotechnology, molecular biology, and biomedical engineering, the domain of nanotheranostics has been steadily evolving by continuously transforming our conception of imaging and therapeutic applications. While existing technologies have already achieved remarkable feats in integrating both therapies and diagnostics, newer emerging systems are poised to elevate their efficacy, precision, and clinical significance. More intelligent and more responsive nanocarriers that can adjust to changing biological environments and deliver site-specific therapeutic interventions are being focused on for progressive development by many researchers. The central theme guiding this trajectory is the fulfilment of the precision medicine paradigm, the precise customisation of therapies based on individual physiological and genetic makeup[14]. The integration of AI-guided nanomedicine design is a novel pathway for advancing nanotheranostics. The utilization of computational modeling and machine learning is rapidly gaining momentum for predicting nanoparticle behavior, refining nanomaterials, and designing optimized delivery strategies. When AI digs into massive datasets—from how we synthesize nanoparticles to how they interact with the body and play out in clinical settings—it uncovers patterns we'd miss on our own. This lets scientists fine-tune things like size, shape, surface chemistry, and loading capacity to fit a specific medical need. Predictive models are expected to accelerate nanotheranostics development by reducing labor costs and enhancing translation potential. In conjunction with imaging techniques, AI may also augment diagnostic outcomes and monitor therapeutic progression in real-time[25].

A new trend in the development of novel nanotheranostics systems, which aim to replicate biological structures, is biomimetic nanoparticles, by which the biocompatibility and targeted delivery efficiency can be enhanced. To design such carriers, natural cell membranes (such as from red blood cells, platelets, immune cells and cancer cells) are utilized to cloak engineered nanomaterials, thereby granting them

properties such as immune evasion and increased circulating half-life. This trick gives the particles a sort of disguise; they dodge the immune system, hang around in the bloodstream longer, and zero in on their targets with more precision. By copying nature's own blueprints, these carriers get better at delivering their payloads right where they're needed and sidestep getting swept up by the immune system. It's a promising approach, one that could push nanomedicine and nanotheranostics to a new level of effectiveness[26].

Gene editing and nucleic acid-based therapy constitute another area where nanotheranostics will play an indispensable role. Newer systems like CRISPR-Cas9 and the use of siRNA/mRNA therapies require efficient targeted delivery, which can be readily achieved with nanoparticles. These platforms can be exploited for the delivery of genetic material while simultaneously being used for imaging and tracing the gene editing process. When combined with diagnostic technologies, these systems could completely revolutionise the detection and treatment of genetic abnormalities, thus enabling future strategies to target genetic disorders, cancer and other complex illnesses[10].

Further enhancing versatility are multifunctional and multimodal nanotheranostics systems, where each nanosystem possesses different therapeutic and diagnostic functionalities. These systems can combine several imaging techniques (MRI, fluorescence, photoacoustic imaging) with diverse therapeutic modalities (chemotherapy, photothermal therapy, immunotherapy). Such an approach offers an inclusive view into the diagnostic possibilities while concurrently providing combination therapy options. Such advanced platforms are paramount when it comes to complex and hard-to-treat diseases like cancer[11].

The synergistic coupling of nanotheranostics and immunotherapy presents a burgeoning field of investigation. Immunotherapy has witnessed a substantial development as a strategy to manage a variety of cancers by harnessing the body's own immune mechanisms. Nanoparticle-mediated theranostic systems may complement immunotherapy by enabling targeted delivery of immune-stimulating agents at the tumor site while enabling monitoring of tumor immune response. Nanoparticles can be utilized for targeted delivery of immune checkpoints, cancer vaccines, or cytokines while concurrently providing visualization into immune cell distribution and tumor regression. These advancements have the potential to improve the overall efficacy of immunotherapy while significantly reducing the incidence of its systemic adverse effects[14].

Personalized nanomedicine strategies coupled with novel fields like genomics, proteomics and metabolomics are other significant research directions. With detailed analysis of the molecular profile of each individual, researchers could potentially develop nanotheranostics tailored to specific disease characteristics. Such a personalized strategy allows for the delivery of individualised therapy tailored to distinct genetic and molecular profiles while simultaneously facilitating monitoring of therapeutic response through imaging and biomarker analysis. This personalization can contribute to a transformational approach towards treatment, whereby therapeutic strategies would maximize the outcomes and minimize the side effects[25].

Real progress in nanotheranostics depends on people from different fields—scientists, doctors, engineers, even regulators—working closely together. We need better nanomaterials, sharper imaging, smarter algorithms, and advanced molecular diagnostics if we want these promising technologies to actually make it into hospitals and clinics. As new breakthroughs keep coming, nanotheranostics will only become more important in precision medicine, helping us catch diseases earlier, treat them more accurately, and tailor care for every patient.

Conclusion

Nanotheranostics is an exceptionally promising modality for merging diagnostics and therapeutics in a unified nanoscale framework, presenting outstanding advantages for precision medicine. Significant progress made in nanobiotechnology has provided a platform for the development of multi-functional nanomaterials, which are efficient in targeted delivery of therapeutic agents, multi-modal imaging and real-time monitoring of treatment outcome. This expansion has further pushed the applications of nanotheranostics for the treatment of chronic disorders such as cancer, neurological and cardiovascular diseases, as well as infectious diseases, and has shown prospects for personalized medicine applications.

However, current efforts on nano-toxicity, biodistribution and scalability of the manufacturing process of nanomaterials, as well as acquisition of regulatory approval, hinder the translation of nanotheranostics to the clinical setting. Continuous development in nanomaterial engineering, interaction with biological systems and multi-disciplinary collaborations is of utmost importance to overcome the current challenges. Therefore, nanotheranostics is projected to serve an increased role in future precision medicine due to consistent progress in research and implementation strategies for reliable nanotheranostic applications.

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Alassisted tools were utilized solely for language refinement and structural organization in the development of this manuscript. The authors independently verified, edited, and approved all sections of the final content.

Conflict of Interest

Not Applicable.

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