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Review Article

Regenerative medicine approaches for solid tumors: A review of current research and clinical trials in India

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Abstract

Solid tumors remain a major cause of global cancer morbidity and mortality due to tumor heterogeneity, therapeutic resistance, metastatic progression, and disease recurrence. Regenerative medicine has emerged as a rapidly evolving interdisciplinary field integrating stem cell biology, biomaterials, tissue engineering, and cell-free therapeutic platforms, offering novel opportunities to modulate the tumor microenvironment and enhance therapeutic precision. At the same time, the biological overlap between regenerative and oncogenic signaling introduces significant translational complexity and safety concerns. This narrative review synthesizes contemporary global and Indian research on regenerative medicine approaches applied to solid tumors, with emphasis on stem cell–based therapeutic delivery, exosome and secretome platforms, tissue-engineered three-dimensional tumor models, engineered vasculature systems, cancer stem cell biology, and tumor microenvironment modulation. Mesenchymal stem cell–based strategies demonstrate tumor-homing capability and targeted delivery of chemotherapeutic agents, cytokines, and oncolytic viruses, while exosome-mediated molecular transfer offers a promising cell-free alternative for therapeutic modulation. Tissue engineering and vascularized tumor models provide physiologically relevant platforms for studying tumor behavior, drug penetration, and immune interactions. Despite these advances, major challenges persist, including tumorigenicity risk, immune suppression, variability in biomaterial systems, lack of standardization in exosome manufacturing, and regulatory uncertainty. Within the Indian research ecosystem, regenerative oncology is characterized by strong conceptual and preclinical foundations but limited structured clinical translation due to infrastructural constraints, funding limitations, regulatory delays, and lack of large multicentric trials. Regenerative medicine holds significant promise as a transformative adjunct to conventional solid tumor therapy by improving targeting accuracy, overcoming resistance mechanisms, and supporting post-oncologic tissue repair. However, its safe and effective clinical integration will require rigorous biosafety validation, standardized manufacturing pipelines, harmonized regulatory frameworks, and coordinated translational infrastructure.

Keywords: Solid tumors, Regenerative medicine, Cancer stem cell, Engineered vasculature, Oncology, Tissue engineering

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1. Introduction

Solid tumors account for the majority of global cancer-related morbidity and mortality and continue to pose major therapeutic challenges despite advances in surgery, chemotherapy, radiotherapy, targeted therapy, and immunotherapy.[1,2] Tumor heterogeneity, therapeutic resistance, disease recurrence, and metastatic progression remain central barriers to long-term disease control.[1,2]

Regenerative medicine has emerged as a transformative interdisciplinary field with the potential to redefine cancer therapeutics through strategies that restore, replace, or modulate damaged cellular and tissue environments.[3–6] This field encompasses stem cell–based therapies, tissue engineering, biomaterials, gene editing technologies, extracellular vesicle–based interventions, and advanced three-dimensional biological platforms.[3–5]

The interface between regenerative medicine and oncology is biologically complex and inherently paradoxical. The defining properties of regenerative systems—self-renewal, differentiation, and plasticity—overlap closely with the fundamental characteristics of cancer stem cells that drive tumor initiation, therapeutic resistance, and relapse in solid tumors.[7–9] This duality highlights both the therapeutic promise and oncogenic risks associated with regenerative strategies.[1,9]

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Among regenerative approaches, stem cell–based strategies have received the greatest attention in oncology. Mesenchymal stem cells exhibit tumor-homing capacity, immunomodulatory effects, and the ability to function as cellular delivery vehicles for anticancer agents.[10–13] These properties have positioned stem cell–based platforms as attractive candidates for targeted therapeutic delivery in solid tumors.

Parallel advances in cell-free regenerative platforms, particularly stem cell–derived exosomes and secretomes, have expanded therapeutic possibilities by enabling targeted biological signaling while minimizing the risks associated with live-cell transplantation.[14,15] These approaches have demonstrated potential in regulating tumor growth, angiogenesis, immune modulation, and drug resistance in experimental solid tumor models.[14,15]

Tissue engineering and biomaterial-based strategies further extend the scope of regenerative oncology by enabling the creation of physiologically relevant tumor microenvironment models. Vascularized three-dimensional constructs, engineered vasculature, microfluidic tumor platforms, and organ-on-chip technologies now allow precise interrogation of tumor–stromal interactions, angiogenesis, drug penetration, and therapeutic response under near-physiological conditions.[5,16]

Solid tumors represent a particularly relevant target for regenerative medicine due to their dependence on stromal remodeling, aberrant angiogenesis, immune evasion, and extracellular matrix dynamics.[1,2,16] Regenerative strategies designed to reprogram these processes offer novel therapeutic avenues, but also introduce significant safety concerns related to oncogenic transformation, unintended stimulation of tumor growth, and long-term genomic instability.[1,9,15]

India occupies a strategically important position in the evolving regenerative medicine landscape. The country faces a rapidly rising burden of solid tumors alongside expanding biotechnology capabilities, increasing translational research output, and evolving regulatory frameworks for stem cell–based interventions.[6,13,17] Indian scientific contributions to cancer stem cell biology and regenerative concepts in oncology are reflected in national biomedical literature.[6–8] However, despite this conceptual and experimental foundation, the clinical translation of regenerative medicine approaches for solid tumor management in India remains at an early and heterogeneous stage.[13,17]

This review aims to synthesize the current evidence on regenerative medicine approaches applied to solid tumors, with particular emphasis on research developments, technological innovations, and translational efforts relevant to the Indian context. By integrating global scientific advances with India-specific perspectives, this review seeks to highlight therapeutic opportunities, biological limitations, regulatory considerations, and critical knowledge gaps that must be addressed for the safe and effective clinical adoption of regenerative medicine strategies in solid tumor oncology.[1–18]

2. Materials and Methods

This review was conducted as a narrative synthesis of the existing literature focusing on regenerative medicine approaches applied to solid tumors, with particular emphasis on translational relevance and research contributions from India. The scope of regenerative medicine for the purpose of this review included stem cell–based therapies, cell-free regenerative platforms such as extracellular vesicles and secretomes, tissue engineering and biomaterial-based strategies, engineered vasculature systems, and regenerative signaling mechanisms relevant to solid tumor biology.[3–5,14,16]

A comprehensive literature search was performed using multiple electronic databases, including PubMed, PubMed Central, Scopus, Web of Science, Google Scholar, and publisher-specific platforms such as Nature, Springer, Wiley, ACS Publications, Frontiers, and Sage Journals. The search strategy was designed to capture both global advances and Indian research outputs in the field of regenerative oncology. Key search terms included combinations of "regenerative medicine," "stem cell therapy," "mesenchymal stem cells," "exosomes," "secretome," "tissue engineering," "engineered vasculature," "tumor microenvironment," "cancer stem cells," and "solid tumors," along with "India" and "Indian studies" where applicable.[1–18]

The time frame for the primary search encompassed publications from 2015 to 2025 to ensure inclusion of both foundational concepts and recent technological advances in regenerative medicine. Priority was given to peer-reviewed original research articles, systematic and narrative reviews, and high-impact translational studies relevant to solid tumor biology and therapy. Editorials and conceptual perspectives were included selectively when they provided critical mechanistic insights into cancer stem cells, regenerative signaling pathways, and safety concerns associated with regenerative strategies in oncology.[6,8,9]

To ensure direct relevance to the scope of this review, studies were included if they met one or more of the following criteria:

1. Investigation of stem cell–based or cell-free regenerative approaches in solid tumor models.
2. Evaluation of tissue engineering or engineered vasculature platforms relevant to tumor microenvironment modeling.
3. Analysis of cancer stem cell biology in the context of regenerative signaling,
4. Discussion of translational, regulatory, or clinical considerations of regenerative medicine in oncology, particularly within the Indian context.[1,2,6,7,10–13,15,16,18] Studies focusing exclusively on hematological malignancies, non-oncologic regenerative applications, or purely market-based analyses without scientific data were excluded.

Special emphasis was placed on identifying Indian contributions to the field, including experimental studies, clinical observations, and conceptual frameworks originating from Indian institutions.[6–8,13,17] Although large-scale randomized clinical trials of regenerative medicine for solid tumors in India were found to be limited, Indian-authored studies provided important mechanistic and translational perspectives that were incorporated into the synthesis.

Table 1: Major regenerative medicine modalities relevant to solid tumors

Modality	Core mechanism	Application in solid tumors	Key limitations
Mesenchymal stem cells (MSCs)	Tumor homing, immunomodulation	Targeted drug/gene delivery, stromal modulation	Tumor-promoting risk.[9–11]
Induced pluripotent stem cells (iPSCs)	Cellular reprogramming	Tumor modeling, drug testing	Teratoma, genomic instability.[3,6]
Exosomes & secretome	Molecular cargo transfer	Drug delivery, immune modulation	Standardization, dual effects.[14,15]
Biomaterial scaffolds	ECM mimicry	3D tumor modeling, reconstruction	Scalability, reproducibility.[5,16]
Engineered vasculature	Angiogenesis modeling	Drug perfusion studies	Technical complexity.[12,16]

All selected articles were screened manually for relevance based on title and abstract, followed by full-text evaluation. Data were extracted qualitatively, focusing on regenerative modality, solid tumor type, experimental or clinical model, biological mechanisms, therapeutic implications, and reported limitations. Given the heterogeneity of study designs and the predominance of preclinical and early translational data, a formal meta-analysis was not undertaken. Instead, findings were synthesized descriptively to provide an integrated overview of regenerative medicine strategies in solid tumor oncology and their current status within the Indian research landscape.[1–18]

3. Overview of Regenerative Medicine Modalities in Solid Tumors

Regenerative medicine encompasses stem cell–based therapies, cell-free vesicular platforms, tissue engineering, biomaterials, and engineered vasculature systems that collectively influence solid tumor biology and therapeutic response.[3–5,16] The major regenerative modalities relevant to solid tumors and their translational implications are summarized in **Table 1**. Among these, mesenchymal stem cells dominate translational research due to their tumor-tropic behavior and immunomodulatory capacity.[10,11] Parallel advances in exosome-based platforms and biomaterial-engineered tumor models have further expanded the scope of regenerative oncology.[14–16] However, shared biological signaling between regeneration and oncogenesis introduces inherent safety risks that constrain indiscriminate clinical application.[1,9] **(Table 1)**

This schematic illustrates the major regenerative medicine modalities interacting within the solid tumor microenvironment. Mesenchymal Stem Cells (MSCs) exhibit tumor-homing behavior and deliver therapeutic cargo directly to the tumor mass. Exosomes derived from stem cells and tumor cells mediate molecular cargo transfer, including microRNAs, proteins, and drug payloads, influencing tumor growth, immune modulation, and therapeutic response. Cancer stem cells within the tumor core drive self-renewal, therapy resistance, and disease recurrence. Biomaterial scaffolds simulate the extracellular matrix and support three-dimensional tumor modeling and drug testing. Engineered and abnormal tumor vasculature facilitates angiogenesis, nutrient delivery, and therapeutic transport. Immune cells within the microenvironment exhibit suppressed or activated functional states depending on regenerative and tumor-derived signaling. All components interact dynamically within the extracellular matrix–rich tumor microenvironment to regulate solid tumor progression and therapeutic response.

3.1. Cancer stem cells and regenerative signaling in solid tumors

Cancer stem cells are now recognized as the central drivers of solid tumor initiation, therapeutic resistance, and relapse.[7–9] These cells exploit regenerative signaling pathways that normally regulate tissue repair. The major signaling networks governing CSC maintenance and disease progression are summarized in **Table 2**. Aberrant activation of Wnt, Notch, Hedgehog, and TGF-β signaling enables CSCs to survive cytotoxic stress, maintain plasticity, and drive metastatic dissemination.[1,9] Regenerative platforms offer powerful tools for dissecting CSC niche dynamics, yet inappropriate activation of these same pathways also carries oncogenic risk.[6,9] **(Table 2)**

Table 2: Key regenerative signaling pathways active in cancer stem cells

Pathway	Primary function	Clinical impact
Wnt/β-catenin	Self-renewal	Drug resistance
Notch	Asymmetric cell division	Tumor recurrence
Hedgehog	EMT induction	Metastasis
TGF-β	Immune suppression	Tumor progression

This schematic depicts the major regenerative and microenvironmental signaling pathways that converge on cancer stem cells (CSCs) to sustain malignant behavior in solid tumors. Wnt/β-catenin signaling promotes CSC self-renewal, while Notch regulates asymmetric cell division and stemness maintenance. Hedgehog signaling drives epithelial–mesenchymal transition and invasive potential. Transforming growth factor-β (TGF-β) mediates immune suppression and supports tumor immune escape. Hypoxia within the tumor microenvironment enhances CSC survival and therapy resistance. Collectively, activation of these pathways results in key downstream clinical consequences, including drug resistance, metastatic dissemination, and tumor recurrence.

Table 3: Stem cell–based therapeutic strategies in solid tumors

Strategy	Therapeutic payload	Antitumor effect	Key risk
MSC-drug loading	Chemotherapy	Targeted cytotoxicity	Off-target effects
MSC-gene therapy	TRAIL, IFNs	Apoptosis induction	Genetic instability
MSC-virus delivery	Oncolytic viruses	Tumor lysis	Immune toxicity

Table 4: Therapeutic applications of exosomes in solid tumors

Exosomal cargo	Function	Therapeutic role
microRNAs	Gene silencing	Drug sensitization
Proteins	Apoptosis induction	Tumor regression
siRNA	Gene knockdown	Targeted therapy

3.2. Stem cell–based therapeutic strategies in solid tumors

Stem cell–based strategies in solid tumors are primarily centered on mesenchymal stem cells due to their intrinsic tumor-homing capacity and compatibility with molecular payloads.[10,11] The principal stem cell–mediated therapeutic strategies are summarized in **Table 3**. Engineered MSCs have demonstrated the ability to induce apoptosis, suppress angiogenesis, and enhance chemosensitivity in multiple solid tumor models.[11,12] However, context-dependent tumor-promoting effects, immune suppression, and biosafety concerns continue to limit widespread clinical adoption.[9,14] In India, stem cell–based regenerative oncology remains largely preclinical with limited structured interventional trials.[13,17] **(Table 3)**

This schematic illustrates mesenchymal stem cell (MSC)–mediated targeted therapeutic delivery to solid tumors following systemic administration. MSCs circulating within the bloodstream exhibit tumor-homing behavior and migrate preferentially toward the tumor microenvironment. Engineered MSCs serve as cellular carriers for multiple anticancer payloads, including chemotherapeutic agents, tumor necrosis factor–related apoptosis-inducing ligand (TRAIL) and interferons (IFNs), as well as oncolytic viruses. Upon reaching the tumor, MSCs release these therapeutic agents, leading to tumor cell apoptosis, suppression of angiogenesis, and activation of antitumor immune responses. The side panel highlights potential context-dependent risks associated with MSC-based therapy, including immune suppression and inadvertent tumor-supportive effects under specific microenvironmental conditions.

3.3. Cell-free regenerative platforms: exosomes and secretomes

Cell-free regenerative platforms, particularly stem cell–derived exosomes, offer targeted molecular delivery with superior biosafety compared to live-cell therapies.[14,15] The principal therapeutic mechanisms mediated by exosomal cargo are summarized in **Table 4** Exosomes regulate angiogenesis, immune modulation, drug resistance, and metastatic niche formation within the solid tumor microenvironment.[2,14] Despite strong preclinical efficacy, challenges related to manufacturing standardization, cargo control, and regulatory classification continue to limit clinical translation, particularly in India.[6,13,15] **(Table 4)**

This schematic illustrates the role of exosomes as key mediators of cell-free regenerative signaling within the solid tumor microenvironment. Exosomes released from mesenchymal stem cells (MSCs) and tumor cells carry functional molecular cargo, including microRNAs (miRNA), proteins, and small interfering RNA (siRNA). These vesicles are transferred to target cells within the tumor microenvironment, where they modulate multiple oncologic processes. Exosome-mediated signaling influences angiogenesis, immune suppression or activation, tumor cell drug sensitivity, and the formation of pre-metastatic and metastatic niches. The biological effects of exosomes are highly dependent on their cellular source and molecular cargo composition, highlighting their dual therapeutic and tumor-promoting potential in regenerative oncology.

3.4. Tissue engineering, biomaterials, and engineered vasculature in solid tumors

Tissue engineering and biomaterial-based strategies constitute a central pillar of regenerative medicine with increasing relevance to solid tumor research, therapy optimization, and post-oncologic reconstruction. These approaches integrate cells, bioactive molecules, and three-dimensional scaffolding systems to recapitulate tissue architecture and microenvironmental dynamics under controlled experimental and translational conditions.[3–5,16] In solid tumors, where extracellular matrix remodeling, stromal interactions, and angiogenesis critically influence disease progression and therapeutic response, tissue engineering platforms provide a powerful interface between regenerative biology and oncology.

Biomaterial scaffolds form the structural foundation of most tissue-engineering systems. Natural polymers such as collagen, fibrin, chitosan, and hyaluronic acid, along with synthetic materials including polylactic acid, polyglycolic acid, and polyethylene glycol, are widely used to construct three-dimensional tumor models and regenerative constructs.[5,16] These materials can be engineered to mimic the mechanical stiffness, porosity, and biochemical composition of native tumor tissues. Alterations in matrix stiffness and architecture are known to regulate tumor cell migration, invasion, epithelial–mesenchymal transition, and resistance to therapy, making biomaterial platforms particularly valuable for mechanistic studies in solid tumors.[2,16]

Three-dimensional tumor models derived from tissue-engineered scaffolds have substantially advanced the study of solid tumor biology beyond conventional two-dimensional cultures. These models more accurately reproduce hypoxic gradients, nutrient diffusion barriers, stromal heterogeneity, and drug-penetration limitations encountered in vivo.[5,16] As a result, they enable realistic evaluation of chemotherapeutic efficacy, radiation sensitivity, and resistance mechanisms. Importantly, these platforms have also facilitated the study of cancer stem cell niche dynamics under physiologically relevant conditions, further strengthening their translational significance.[7,8,16]

Engineered vasculature represents a major advancement within tumor tissue engineering. Angiogenesis is a defining hallmark of solid tumors, governing tumor growth, invasion, and metastatic dissemination.[2,16] Regenerative strategies that incorporate endothelial cells, perivascular support cells, and growth factor gradients allow the formation of functional microvascular networks within engineered tumor constructs. These vascularized platforms enable dynamic investigation of tumor perfusion, intravascular migration, immune cell trafficking, and drug delivery under flow conditions that closely approximate physiological states.[12,16]

Microfluidic tumor-on-chip and organ-on-chip technologies have further refined the interface between tissue engineering and solid tumor research. These systems permit precise control over fluid dynamics, oxygen tension, cell–cell interactions, and spatial organization of tumor and stromal compartments.[12,16] By enabling real-time visualization of tumor invasion, immune interactions, and therapeutic responses, microfluidic platforms have become indispensable tools for precision oncology research and high-throughput drug screening. Their compatibility with patient-derived tumor cells also supports the development of individualized therapeutic testing strategies.[12,16]

From a regenerative medicine perspective, biomaterial-based platforms extend beyond tumor modeling to include post-oncologic tissue reconstruction. Surgical resection of solid tumors often produces extensive tissue defects requiring complex reconstructive interventions, particularly in head and neck, breast, and musculoskeletal malignancies. Regenerative scaffolds seeded with stem cells or functionalized with growth factors are being investigated to enhance wound healing, promote neovascularization, and restore tissue architecture in cancer survivors.[3,5,13] While these applications are not directly antitumor, they underscore the broader clinical relevance of regenerative biomaterials across the cancer care continuum.

Despite their promise, tissue engineering and biomaterial approaches face important translational challenges in solid tumor oncology. Reproducibility of scaffold fabrication, variability in material composition, and standardization of mechanical and biochemical properties remain significant obstacles to large-scale clinical implementation.[5,16] Furthermore, engineered platforms cannot yet fully replicate the systemic immune, endocrine, and metabolic influences that shape tumor behavior in vivo. As such, these systems should be viewed as complementary rather than substitute tools for animal models and clinical trials.[12,16]

In the Indian research context, tissue engineering and biomaterials science is an expanding field with growing relevance to oncology. Indian investigators have contributed to scaffold development, cancer stem cell modeling, and regenerative signaling studies that inform tumor microenvironment research.[6–8] However, the clinical translation of engineered tumor platforms and regenerative biomaterials into structured solid tumor trials remains limited.[13,17] Constraints related to manufacturing infrastructure, interdisciplinary integration, and regulatory approval pathways continue to restrict rapid clinical deployment of these technologies in India.[6,13]

The regulatory oversight of tissue-engineered and biomaterial-based products in oncology also remains an evolving domain. Classification of these constructs as medical devices, biological products, or combination therapies varies across jurisdictions, creating ambiguity in translational pathways.[6] In India, dedicated regulatory frameworks for advanced tissue-engineered oncologic products are still developing, which contributes to delays in clinical translation despite robust preclinical innovation.[6]

In summary, tissue engineering, biomaterials, and engineered vasculature platforms represent indispensable regenerative medicine modalities for advancing solid tumor research, therapeutic optimization, and post-oncologic reconstruction.[3–5,12,16] These technologies provide physiologically relevant systems for studying tumor microenvironment dynamics, cancer stem cell niches, angiogenesis, and drug resistance while also supporting reconstructive regenerative applications in cancer care. However, limitations in standardization, scalability, and regulatory clarity continue to constrain their full clinical integration, particularly within the Indian translational research ecosystem.[6,13,17]

This figure illustrates a comparative representation of conventional two-dimensional (2D) tumor culture systems and three-dimensional (3D) tissue-engineered and vascularized tumor models. The 2D tumor model demonstrates uniform drug exposure, absence of extracellular matrix, lack of vascular supply, and poor immune representation, resulting in an overestimation of therapeutic drug efficacy. In contrast, the 3D tissue-engineered tumor model incorporates a biomaterial scaffold that mimics the extracellular matrix, engineered vasculature for nutrient and oxygen delivery, immune cell trafficking, and a hypoxic tumor core. These features generate realistic drug penetration gradients and reproduce physiological drug resistance patterns. Collectively, 3D vascularized platforms provide a more accurate and translationally relevant representation of solid tumor biology and therapeutic response than conventional 2D systems. **(Figure 1)**

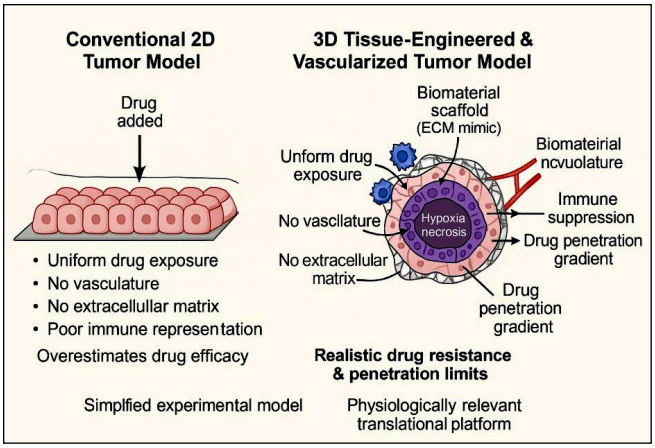

Figure 1: Tissue-engineered tumor models and engineered vasculature platforms

3.4. Tumor microenvironment modulation and regenerative cross-talk

The tumor microenvironment constitutes a highly dynamic and heterogeneous ecosystem composed of malignant cells, stromal fibroblasts, endothelial cells, immune cells, extracellular matrix components, and soluble signaling mediators. In solid tumors, continuous bidirectional cross-talk between these components governs tumor initiation, progression, immune evasion, angiogenesis, and therapeutic resistance.[2,16] From a regenerative medicine perspective, this complex microenvironment represents both a target and a regulator of regenerative signaling, positioning it at the center of translational regenerative oncology.

Regenerative signaling pathways that govern physiological tissue repair, including transforming growth factor-β, Wnt/β-catenin, Hedgehog, Notch, and fibroblast growth factor pathways, are aberrantly activated within the solid tumor microenvironment.[1,8,9] These pathways regulate cellular plasticity, epithelial–mesenchymal transition, angiogenesis, and immune modulation. Their dysregulated activity promotes tumor cell survival under hypoxic and nutrient-deprived conditions while simultaneously reinforcing cancer stem cell niches that fuel therapeutic resistance and relapse.[2,7,9] Consequently, the tumor microenvironment functions not merely as a passive scaffold, but as a regenerative-like niche that actively sustains malignant regeneration.

Stromal fibroblasts represent a major cellular component of the regenerative tumor microenvironment. Cancer-associated fibroblasts secrete extracellular matrix proteins, cytokines, and growth factors that remodel tissue architecture, enhance tumor cell migration, and regulate immune infiltration.[2,16] These fibroblasts exhibit phenotypic similarities to wound-healing myofibroblasts and participate in regenerative-like remodeling processes that inadvertently support tumor growth. Regenerative medicine platforms that alter fibroblast–tumor interactions therefore hold potential to modulate desmoplasia and improve therapeutic penetration in solid tumors.[5,16]

Angiogenesis represents another core axis of regenerative cross-talk within the tumor microenvironment. Aberrant neovascularization is driven by regenerative growth factors such as vascular endothelial growth factor, platelet-derived growth factor, and angiopoietins, which collectively promote endothelial proliferation, vessel permeability, and metastatic dissemination.[2,16] Engineered vasculature platforms and biomaterial-based angiogenic models have demonstrated that tumor-derived regenerative signals generate structurally abnormal, leaky vascular networks that compromise effective drug delivery and immune cell trafficking.[12,16] Regenerative modulation of angiogenic signaling therefore represents a critical therapeutic target in solid tumors.

Immune regulation within the tumor microenvironment also reflects regenerative cross-talk. Regenerative cytokines and growth factors shape the recruitment, polarization, and functional state of immune cells, including macrophages, dendritic cells, natural killer cells, and T lymphocytes.[2,14] Tumor-associated macrophages often adopt pro-regenerative, immunosuppressive phenotypes that facilitate tissue remodeling, angiogenesis, and tumor growth. Mesenchymal stem cells and their secretomes further influence immune suppression and tolerance through the secretion of anti-inflammatory mediators and immune checkpoint–associated signaling molecules.[10,14] These interactions contribute to immune escape and limit the efficacy of immunotherapeutic interventions in solid tumors.

Extracellular vesicles serve as central mediators of regenerative cross-talk within the tumor microenvironment. Tumor-derived and stem cell–derived exosomes transfer regulatory RNA species, metabolic enzymes, and signaling proteins across cellular compartments, thereby coordinating angiogenesis, immune modulation, and stromal activation.[14,15] These vesicles actively participate in the formation of pre-metastatic niches at distant organ sites and promote metastatic colonization through regenerative matrix remodeling and immune priming.[2,14] Conversely, engineered regenerative exosomes offer the potential to reprogram the microenvironment toward antitumor immunity and enhanced chemosensitivity.[15]

Regenerative modulation of the extracellular matrix further influences solid tumor behavior. Matrix stiffness, collagen alignment, and proteolytic remodeling regulate tumor cell migration, invasion, and epithelial–mesenchymal transition.[2,16] Biomaterial-based regenerative platforms have demonstrated that controlled alteration of matrix composition and mechanical cues can suppress invasive phenotypes and enhance therapeutic response in solid tumor models.[5,16] These findings emphasize the importance of physical as well as biochemical regulation within the regenerative tumor microenvironment.

From a translational perspective, targeting tumor microenvironment–regenerative cross-talk has emerged as a complementary strategy to direct tumor cell–targeted therapies. Disruption of pro-regenerative stromal signaling,

normalization of abnormal vasculature, reprogramming of immune cell phenotypes, and modulation of extracellular matrix dynamics can collectively enhance the efficacy of chemotherapy, radiotherapy, targeted therapy, and immunotherapy.[1,2,16] Regenerative medicine platforms provide experimental systems to systematically evaluate these combinatorial approaches under physiologically relevant conditions.[12,16]

Within the Indian research ecosystem, investigations into tumor microenvironment biology and regenerative signaling are steadily expanding. Indian studies on cancer stem cell niches, stromal remodeling, and regenerative cytokine networks have contributed valuable mechanistic insights into solid tumor progression.[6–8] However, translational efforts aimed at therapeutically modulating tumor microenvironment–regenerative cross-talk in Indian patient cohorts remain limited.[13,17] Multidisciplinary integration of oncology, immunology, biomaterials engineering, and regenerative biology will be essential to accelerate progress in this domain.

In summary, the tumor microenvironment represents a regenerative signaling–rich ecosystem that dynamically orchestrates solid tumor progression, immune evasion, angiogenesis, and therapeutic resistance.[2,16] Regenerative cross-talk between tumor cells, stromal fibroblasts, immune populations, vascular endothelium, and extracellular vesicles sustains malignant regeneration through pathways that mirror physiological tissue repair.[1,9,14] Targeting these regenerative regulatory networks offers promising opportunities for therapeutic intervention while also introducing substantial biological complexity. A refined understanding of tumor microenvironment–regenerative integration will therefore be critical for the rational development of regenerative medicine strategies in solid tumor oncology, particularly within the evolving Indian translational research landscape.[1–18]

3.5. Indian research landscape in regenerative oncology

India represents a uniquely positioned and rapidly evolving ecosystem for regenerative medicine research, driven by a large cancer burden, expanding biotechnology infrastructure, and increasing academic interest in translational oncology. Solid tumors constitute the dominant share of cancer incidence in India, creating an urgent clinical need for innovative therapeutic platforms that extend beyond conventional surgery, chemotherapy, and radiotherapy.[13,17] Within this context, regenerative medicine has emerged as a promising yet still largely experimental domain in Indian oncology research.

Indian contributions to regenerative oncology have been most prominent at the level of fundamental cancer stem cell biology and regenerative signaling mechanisms. Indian investigators have played an important role in characterizing cancer stem cell markers, self-renewal pathways, and niche-dependent signaling across multiple solid tumors.[6–8] These studies have strengthened the conceptual foundation for regenerative strategies by elucidating how stemness, plasticity, and microenvironmental regulation contribute to therapeutic resistance and disease recurrence in Indian patient populations. However, the majority of these contributions remain confined to laboratory-based investigations rather than structured interventional trials.[13,17]

Preclinical research involving mesenchymal stem cells and regenerative signaling modulation has also gained momentum within Indian academic institutions. Experimental studies have explored the interaction between stem cells and solid tumor microenvironments, highlighting both antitumor and tumor-supportive effects depending on biological context.[10,11,14] These findings align closely with global observations of the dualistic behavior of regenerative platforms in oncology and reinforce the need for cautious translational interpretation. Nevertheless, large-scale, standardized animal studies evaluating safety, biodistribution, and long-term oncogenic risk remain limited within the Indian research landscape.[6,13]

Exosome and secretome-based regenerative platforms are an emerging area of interest in India, although they remain at an early developmental stage. Indian researchers have contributed conceptually to the understanding of extracellular vesicle biology, regenerative intercellular communication, and cancer stem cell–mediated signaling.[6–8] However, robust translational pipelines for exosome production, molecular cargo control, and therapeutic validation in solid tumor models are still underdeveloped.[6,13,15] Infrastructure constraints related to Good Manufacturing Practice–compliant production, advanced molecular characterization, and long-term biosafety monitoring currently limit the rapid clinical expansion of these technologies.

Tissue engineering and biomaterials research constitutes one of the most rapidly advancing areas of regenerative science in India with growing relevance to oncology. Indian research groups have developed scaffold systems, hydrogel constructs, and extracellular matrix–mimetic biomaterials for tumor modeling, wound healing, and reconstructive applications.[5,6,13] These platforms are increasingly being integrated with cancer stem cell studies and tumor microenvironment modeling to better understand solid tumor behavior under physiologically relevant conditions.[3,16] Despite strong innovation at the preclinical level, clinical translation into structured oncologic trials remains sparse.[13,17]

From a regulatory perspective, India has established national guidelines governing stem cell research and clinical application through centralized regulatory bodies.[6] These frameworks emphasize ethical sourcing, informed consent, manufacturing standardization, and long-term follow-up for cell-based therapies. However, specific regulatory pathways for advanced regenerative oncology products such as gene-modified stem cells, exosome-based therapeutics, and hybrid biomaterial–cell constructs remain insufficiently harmonized with global standards.[6] This regulatory uncertainty continues to slow down clinical trial approvals and industry-led translational initiatives.

Clinical integration of regenerative medicine into solid tumor management in India remains limited and highly heterogeneous. Most clinical activity involving regenerative platforms has focused on supportive and reconstructive applications rather than direct antitumor intervention. Stem cell–based reconstructive strategies have been explored for post-surgical tissue repair, wound healing, and functional restoration in selected malignancies.[3,5,13] In contrast, rigorously designed interventional trials evaluating stem cell–based drug delivery, exosome therapeutics, or regenerative microenvironment modulation in Indian solid tumor patients are currently scarce.[13,17]

The industrial and translational biotechnology sector in India is gradually expanding its involvement in regenerative medicine; however, oncology-directed regenerative product pipelines remain at a nascent stage. Challenges related to funding, regulatory navigation, intellectual property protection, and long-term safety validation continue to restrict rapid commercialization of regenerative oncology platforms.[6,13] Furthermore, the absence of large-scale multicentric trial networks dedicated to regenerative medicine in cancer limits the generation of high-quality clinical evidence needed to support widespread adoption.

Despite these challenges, India possesses several strategic advantages that could accelerate regenerative oncology translation in the coming decade. These include a vast and genetically diverse patient population, increasing digital health integration, expanding cancer registries, growing public–private research partnerships, and rising investment in biomedical innovation.[13,17] With appropriate regulatory streamlining, infrastructure development, and interdisciplinary collaboration, India has the potential to emerge as a significant contributor to global regenerative oncology research.

In summary, the Indian research landscape in regenerative oncology is characterized by strong conceptual and preclinical foundations but limited structured clinical translation.[6–8,13,17] Advances in cancer stem cell biology, biomaterials science, and regenerative signaling studies have positioned India to make meaningful contributions to this evolving field. However, the transition from experimental promise to routine clinical integration will depend on regulatory harmonization, standardized manufacturing pipelines, multicenter clinical trial infrastructure, and sustained investment in translational regenerative medicine for solid tumors.

This figure illustrates the stepwise translational pathway of regenerative oncology research in India, progressing from basic research through preclinical studies, regulatory approval, clinical trials, and eventual clinical adoption. Basic research encompasses fundamental studies on cancer stem cells, regenerative signaling, biomaterials, and exosomes, which advance into preclinical validation using in vitro and animal models. Transition to human application requires regulatory oversight, followed by phased clinical trials to establish safety and efficacy before integration into routine oncology practice. Major barriers limiting efficient translation are highlighted at critical transition points, including limited Good Manufacturing Practice (GMP)–compliant manufacturing infrastructure, regulatory delays, restricted funding for translational trials, and the lack of large multicentric clinical trial networks. A feedback loop from clinical trials back to basic research emphasizes the iterative nature of scientific refinement within the Indian translational ecosystem.

3.6. Challenges, risks, and regulatory considerations

Despite the rapidly expanding scientific interest in regenerative medicine for solid tumors, multiple biological, technical, ethical, and regulatory challenges continue to limit its routine clinical translation. A central biological concern is the intrinsic overlap between regenerative signaling and oncogenic pathways. Many of the molecular circuits that drive tissue repair—including Wnt/β-catenin, Notch, Hedgehog, and TGF-β signaling—are also implicated in cancer stem cell maintenance, epithelial–mesenchymal transition, and therapeutic resistance.[1,8,9] Therapeutic manipulation of these pathways therefore carries an inherent risk of promoting malignant behavior when not precisely controlled.

Tumorigenicity represents one of the most significant safety concerns associated with stem cell–based regenerative strategies. Mesenchymal stem cells, while widely regarded as relatively safe, exhibit context-dependent dual behavior and may enhance angiogenesis, immune evasion, and cancer stem cell niche stability under certain conditions.[10,11,14] Pluripotent stem cells and induced pluripotent stem cells carry even greater risks related to teratoma formation, genomic instability, and uncontrolled differentiation.[3,16] These risks necessitate extensive preclinical safety validation, long-term follow-up protocols, and rigorous genetic stability testing prior to clinical application in solid tumor patients.

Cell-free regenerative platforms such as exosomes offer improved biosafety relative to live-cell therapies, but they introduce distinct translational challenges. Exosomes exhibit significant heterogeneity in size, cargo composition, and biological effect depending on cell source, culture conditions, and isolation technique.[14,15] Their dual capacity to either suppress or promote tumor progression further complicates therapeutic standardization. Lack of universally accepted protocols for large-scale production, purification, potency testing, and long-term storage remains a major barrier to regulatory approval and clinical deployment.[6,15]

Technical challenges also extend to tissue engineering and biomaterial-based platforms. Variability in scaffold composition, mechanical properties, biodegradation rates, and bioactive functionalization limits reproducibility across laboratories.[5,16] Engineered tumor and vascular models, while powerful for mechanistic discovery and drug screening, cannot yet fully replicate the systemic immune, endocrine, and metabolic influences that govern tumor behavior *in vivo*.[12,16] As a result, translational extrapolation from engineered platforms to human solid tumor therapy must be approached with caution.

Immunological risks represent another critical dimension of regenerative oncology. Stem cells and their secretomes modulate innate and adaptive immunity through multiple mechanisms, including macrophage polarization, T-cell suppression, and cytokine network remodeling.[2,14] While these effects may be therapeutically advantageous in inflammatory and degenerative disorders, they pose significant risks in oncology by facilitating immune escape and reducing the efficacy of immunotherapeutic agents such as immune checkpoint inhibitors.[2] The interaction between regenerative interventions and modern cancer immunotherapy remains incompletely understood and requires careful clinical evaluation.

From an ethical standpoint, the clinical use of regenerative medicine in oncology raises concerns regarding informed consent, therapeutic misrepresentation, and premature commercial exploitation. The global proliferation of unregulated stem cell clinics has contributed to public misunderstanding of regenerative medicine as a proven cancer cure, despite the largely experimental nature of most oncologic applications.[6] This issue is particularly relevant in low- and middle-income settings, where regulatory enforcement may be inconsistent and patients may be vulnerable to unproven interventions.

Regulatory oversight of regenerative medicine products remains highly heterogeneous across global jurisdictions. Classification of regenerative products as drugs, biologics, medical devices, or combination products varies depending on composition and intended use, resulting in complex and often fragmented approval pathways.[6,15] Exosomes, gene-modified stem cells, and hybrid biomaterial–cell constructs pose particular regulatory challenges due to their hybrid biological and engineering features.[6] This regulatory ambiguity delays clinical trial initiation and increases translational uncertainty.

In India, regulatory governance of stem cell research and clinical application is guided by national frameworks emphasizing ethical sourcing, manufacturing standards, and long-term patient monitoring.[6] However, specific regulatory pathways for advanced regenerative oncology products, including exosome-based therapeutics and gene-engineered stem cells, remain insufficiently harmonized with international standards. Limited availability of Good Manufacturing Practice–compliant facilities, constrained biosafety infrastructure, and fragmented approval processes continue to slow the progression of regenerative oncology from bench to bedside.[6,13,17]

Economic and infrastructural barriers further restrict equitable access to regenerative oncology technologies. High costs associated with cell manufacturing, biomaterial fabrication, molecular characterization, and long-term safety surveillance limit scalability, particularly in resource-constrained healthcare systems.[13] The absence of large, multicentric regenerative oncology trial networks in India further constrains the generation of high-quality evidence needed for widespread adoption.[13,17]

Collectively, these biological uncertainties, biosafety risks, technical limitations, ethical concerns, and regulatory challenges define the current translational bottleneck in regenerative medicine for solid tumors.[1,6,9,14,15,17] Addressing these barriers will require coordinated advances in molecular profiling, standardized manufacturing protocols, long-term pharmacovigilance systems, and harmonized regulatory frameworks. Without such safeguards, the clinical integration of regenerative medicine into solid tumor management risks outpacing the evidence required to ensure patient safety and durable therapeutic benefit.

4. Future Directions

The future of regenerative medicine in solid tumor oncology is likely to be shaped by the convergence of stem cell biology, molecular engineering, biomaterials science, and precision oncology. One of the most promising directions lies in the rational integration of regenerative platforms with targeted therapies and immunotherapy. Rather than positioning regenerative medicine as a standalone therapeutic strategy, emerging evidence supports its role as a microenvironment-modulating adjunct that can enhance drug delivery, overcome resistance mechanisms, and improve the durability of immune-mediated tumor control.[1,2,16] Regenerative modulation of stromal signaling, vascular normalization, and immune reprogramming is expected to play an increasingly important role in combination treatment paradigms.

Advances in molecular engineering and gene-editing technologies are likely to further refine the therapeutic precision of regenerative platforms. Gene-modified stem cells and engineered exosomes designed to deliver tumor-suppressive payloads, immune activators, or resistance-modulating RNA species represent a highly promising frontier.[3,14,15] These approaches offer the potential for cell- and pathway-specific intervention within heterogeneous solid tumors, while minimizing systemic toxicity. However, their successful translation will depend on precise cargo control, long-term biosafety validation, and regulatory harmonization.

Patient-specific regenerative tumor models are expected to become central tools in precision oncology. The integration of patient-derived cancer cells with tissue-engineered scaffolds, organoid systems, and vascularized microfluidic platforms will enable individualized assessment of drug sensitivity, resistance patterns, and microenvironmental interactions.[12,16] Such platforms could significantly improve therapeutic selection, reduce unnecessary toxicity, and accelerate personalized treatment strategies in solid tumor management.

Cell-free regenerative platforms, particularly exosome-based therapeutics, are likely to gain increasing prominence due to their favorable biosafety profile, scalability, and compatibility with nanomedicine approaches.[14,15] Continued advances in exosome engineering, surface targeting, and standardized manufacturing are expected to expand their application beyond experimental models toward early-phase

clinical testing in selected solid tumors. Regulatory clarity in this domain will be a critical determinant of translational momentum.

From an Indian perspective, future progress in regenerative oncology will depend heavily on the development of coordinated translational ecosystems. Establishment of centralized Good Manufacturing Practice–compliant cell and exosome production facilities, multidisciplinary regenerative oncology research centers, and multicenter clinical trial networks will be essential to move beyond fragmented, institution-specific efforts.[6,13,17] Strengthening public–private partnerships, streamlining regulatory pathways, and integrating regenerative medicine into national cancer research programs could significantly accelerate clinical translation.

Digital health technologies, artificial intelligence–driven image analysis, and computational modeling are also expected to complement regenerative oncology by enabling high-throughput analysis of tumor–regenerative interactions and treatment response prediction.[12,16] These tools may assist in optimizing scaffold design, vascular modeling, drug penetration dynamics, and immune cell behavior within engineered tumor systems.

Ultimately, the future of regenerative medicine in solid tumor oncology will hinge on the ability to balance innovation with biosafety. As regenerative strategies move closer to clinical application, long-term pharmacovigilance, real-world evidence generation, and adaptive regulatory frameworks will be essential to ensure sustained therapeutic benefit without unintended oncogenic risk.[6,9,15] With coordinated scientific, clinical, and regulatory advancement, regenerative medicine has the potential to evolve from an experimental adjunct into a meaningful component of precision solid tumor therapy.

5. Conclusion

Regenerative medicine has emerged as a powerful and complex frontier in solid tumor oncology, positioned at the intersection of stem cell biology, tissue engineering, molecular therapeutics, and precision oncology. Across multiple solid tumor contexts, regenerative platforms have demonstrated the capacity to modulate tumor microenvironments, enhance targeted drug delivery, support post-oncologic tissue repair, and provide physiologically relevant models for mechanistic discovery and therapeutic testing.[3–5,12,16] At the same time, the shared biological foundations of regeneration and oncogenesis introduce fundamental risks related to cancer stem cell activation, immune modulation, angiogenesis, and therapeutic resistance.[1,2,7,9]

Stem cell–based therapies and cell-free regenerative platforms such as exosomes represent complementary strategies with distinct risk–benefit profiles. While cellular approaches offer tumor-homing and microenvironmental reprogramming capabilities, they carry concerns of tumorigenicity, immune suppression, and genomic instability.[6,9,10,14] Exosome-based systems offer improved biosafety and scalability but face significant challenges related to standardization, cargo control, and regulatory classification.[14,15] Tissue engineering and engineered vasculature platforms have transformed solid tumor modeling and translational research, yet their clinical extrapolation remains constrained by reproducibility and regulatory uncertainties.[5,16]

Within India, regenerative oncology is characterized by strong conceptual and preclinical foundations but limited structured clinical translation.[6–8,13,17] Advances in cancer stem cell biology, biomaterials science, and regenerative signaling research position the country to contribute meaningfully to global progress in this field. However, regulatory harmonization, Good Manufacturing Practice–compliant infrastructure, multicenter clinical trial networks, and sustained translational investment will be essential to bridge the gap between experimental promise and routine clinical application.[6,13,17]

In conclusion, regenerative medicine holds substantial potential to reshape the future of solid tumor research and therapy, not as a replacement for established oncologic treatments, but as a powerful adjunct that can enhance precision, overcome resistance, and improve functional outcomes. Realizing this potential will require coordinated progress in biosafety validation, regulatory governance, and interdisciplinary collaboration to ensure that innovation advances in parallel with patient safety and durable clinical benefit.[6,9,15]

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None.

7. Conflict of Interest

None.

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