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*Original Article*

# Global Innovation Dynamics in Regenerative Medicine: A Patent-Based Assessment

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## Abstract

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**Introduction:** Regenerative medicine (RM) is one of the fastest-growing fields of biomedical innovation. Patent analysis provides valuable insights into technological development and global innovation trends. This study aimed to analyze worldwide patent activity in RM between 2005 and 2025.

**Methods:** This applied study employed a descriptive-analytical patentometric approach. Patent data were retrieved from the Orbit Intelligence database using a structured search strategy that applied the term "RM" to the title, abstract, and claims fields. Granted and expired patent families published between 2005 and 2025 were included, resulting in 10,475 records. The data were retrieved on 25 October 2025, and data cleaning and analysis were performed using Python. Temporal trends, leading countries, major assignees, and technological domains were analyzed.

**Results:** The temporal distribution of patents showed a gradual increase from 2005 to 2012, followed by a pronounced acceleration from 2015 to 2020, during which nearly half of all identified patents were issued. Patent activity peaked in 2018–2019 before experiencing a moderate decline. China (41.41%) and the United States (31.95%) together accounted for nearly three-quarters of all RM patents, highlighting their leading roles in shaping global innovation. South Korea ranked third (8.5%), while Germany, Russia, Japan, the United Kingdom, France, Switzerland, and Canada constituted a secondary group of contributors. Analysis of technological domains indicated that pharmaceuticals, biotechnology, and medical technology represented the most active areas within the RM patent landscape.

**Conclusion:** The findings demonstrate the rapid expansion and consolidation of RM technologies and highlight the value of patent-based intelligence for informing research priorities, investment strategies, technology management, and future innovation in this evolving field.

## Introduction

Regenerative medicine (RM) has emerged as a rapidly evolving interdisciplinary area within the biomedical sciences. It integrates principles of engineering and biological sciences to develop cell based therapies, tissue engineering strategies, gene therapy, and cellular reprogramming approaches aimed at restoring, repairing, or replacing human cells, tissues, and organs to recover normal physiological function (1–3). This field offers considerable potential for treating or replacing tissues and organs damaged by aging, disease, or trauma, as well as for correcting congenital defects. Over the past three decades, RM has evolved from a research domain into a commercial industry, supported by regulatory authorizations and approvals from the U.S. Food and Drug Administration (FDA) (1, 4). The significance of RM extends beyond improving patient outcomes and addressing chronic and complex conditions such as heart failure, diabetes, spinal cord injury, and neurological disorders. It also has a transformative impact on the pharmaceutical and medical industries, leading policymakers and innovation leading countries to recognize it as a strategic domain of interest (2).

Alongside scientific and technological advances, patent registration is widely recognized as an important indicator of innovation. It also serves as a valuable tool for identifying technological trends and shaping innovation strategies (5, 6). Among the various types of patents, granted patents are considered a more reliable and credible indicator of technological maturity and innovative output, as they undergo a more rigorous examination process. Consequently, they tend to have higher credibility and often represent practical innovations with greater economic potential (7).

Although the successful translation of RM therapies from laboratory research to clinical application faces numerous regulatory barriers (8), the field continues to operate within an evolving regulatory landscape. Many of these challenges may be addressed through further advancements in underlying technologies. Therefore, despite existing limitations, the emergence of a more mature and high-value field can be anticipated (9). In recent years, RM technologies have steadily expanded their influence (10). Given the significant clinical and commercial potential of this field, as well as its ongoing progress (2), patent based analyses can provide valuable insights for policymakers, research managers, and industry stakeholders in formulating long term innovation strategies.

A range of studies have examined innovation dynamics in RM and its related technologies, with particular focus on patent activity. Overall, the evidence suggests that this field has experienced substantial growth, with some subdomains exhibiting even exponential increases in patenting activity. For example, a study on intellectual property issues related to animal-derived regenerative implantable medical devices (ADRIMD) found that intellectual property development in this area has not kept pace with scientific and industrial progress. Innovation has been mainly driven by developed countries such as the United States, Germany, the United Kingdom, and France. China, however, has recently entered this field with a narrower focus but a steadily increasing share among the key players (11).

In the field of stem cell-based therapies, despite technological limitations, a stable and increasing trend in innovative activity has been observed. The United States, the European Union, and Australia have been identified as the main hubs for protecting innovations (12). Similarly, an analysis of tissue engineering and RM patents over the period 2010–2020 shows that, although these fields have experienced considerable growth in scientific output and research development, their commercial translation remains limited and less developed than expected (13).

Fatimi et al. reported a significant increase in patenting activity in hydrogel-based biomaterials, with a strong focus on biomedical applications. The average grant rate was approximately 33%, with notable diversity across medical, pharmaceutical, and optical applications. The United States and China were identified as leading countries, while Europe also made a substantial contribution (14). In a related context, an investigation of hydrogel-based bioinks for 3D bioprinting over the period 2013–2024 revealed an upward trend in patenting activity, particularly after 2018. Patent filings in this area are globally distributed, with significant activity observed in the United States, Europe, and Asia (15).

Likewise, a study on organoid technologies reported exponential growth in patenting activity between 2015 and 2020, with an annual growth rate of 67.16%. China and the United States were identified as the main players in this field. However, with different innovation structures, universities played a dominant role in the United States, whereas companies were more influential in China (16). In addition, a scientometric and patentometric study on 3D bioprinting showed substantial growth in both scientific publications and patents, with annual rates of 20% and 40%, respectively. The United States and China led in both domains, and most patents in this field were focused on medical applications (17).

Overall, the evidence shows that RM has experienced sustained growth in patenting activity. In some subfields, it has undergone even faster, accelerated expansion. Moreover, the United States and China have consistently emerged as the leading innovators in this domain. However, previous patent-based studies have primarily focused on specific subfields of RM, such as stem cell therapies, tissue engineering, organoids, hydrogels, and 3D bioprinting, or have examined relatively short time periods. In addition, many of these studies relied on patent applications rather than granted patents or did not provide a comparative analysis of technological domains across countries. Consequently, there remains a lack of a comprehensive and integrated analysis of innovation dynamics across the entire RM field over a long-term period, particularly using granted patents as a more reliable indicator of technological maturity. In addition, comparative studies on the distribution of technological domains across countries remain limited. To address these gaps, this study aims to analyze global innovation trends, identify leading countries, and determine dominant technological domains in RM over the period 2005–2025 based on granted patents.

The specific objectives of this study are to examine the temporal trends in granted patents in RM over the period 2005–2025; to identify the leading countries in RM innovation based on their level of participation in granted patents; to identify the leading technological domains based on the distribution of granted patents and determine which domains exhibit the highest commercialization potential; and to analyze the distribution of technological domains across countries and identify the leading countries within each technology domain.

## Methods

This study adopts an applied research design and follows a descriptive–analytical approach based on granted patent data analysis in the field of RM. Patent records were retrieved from the Orbit Intelligence database. The search strategy used the keyword "regenerative medicine," and the platform's (Orbit Intelligence) recommended keywords (Appendix 1), applied to the title, abstract, and claims fields.

Within the *Family Legal Status* section, only patents with a status of *Granted* or *Expired* within the period 2005–2025 were included. In this study, the term "granted patents" refers to patent documents that have completed the examination process and been granted by the relevant patent office, regardless of whether they remain active or have subsequently expired at the end of their legal term. The data were downloaded on 25 October 2025 in CSV format in batches of 1,000 records. All files were subsequently merged and cleaned using a Python environment. A temporal trend analysis was then conducted using the *Priority Date* field to determine the annual distribution of inventions.

To analyze country-level contributions and identify leading countries and active institutions, the *Assignee Country* field was utilized. Furthermore, the *Technology Domains* labels were used to identify active technological areas and analyze the distribution of technologies across countries.

## Results

### Temporal Analysis

The temporal evolution of granted patents in RM is illustrated in Figure 1. A total of 10,475 patents were identified over the period 2005–2025. The results show a gradual upward trajectory from 2005 to about 2012, followed by a pronounced surge beginning in 2015. Patent activity peaked between 2015 and 2020, during which nearly half of all patents in the dataset were granted. This highest level of activity occurred in 2018–2019, followed by a moderate decline in subsequent years. Overall, the observed trend suggests that RM has progressed from an emergent phase toward a more mature technological domain.

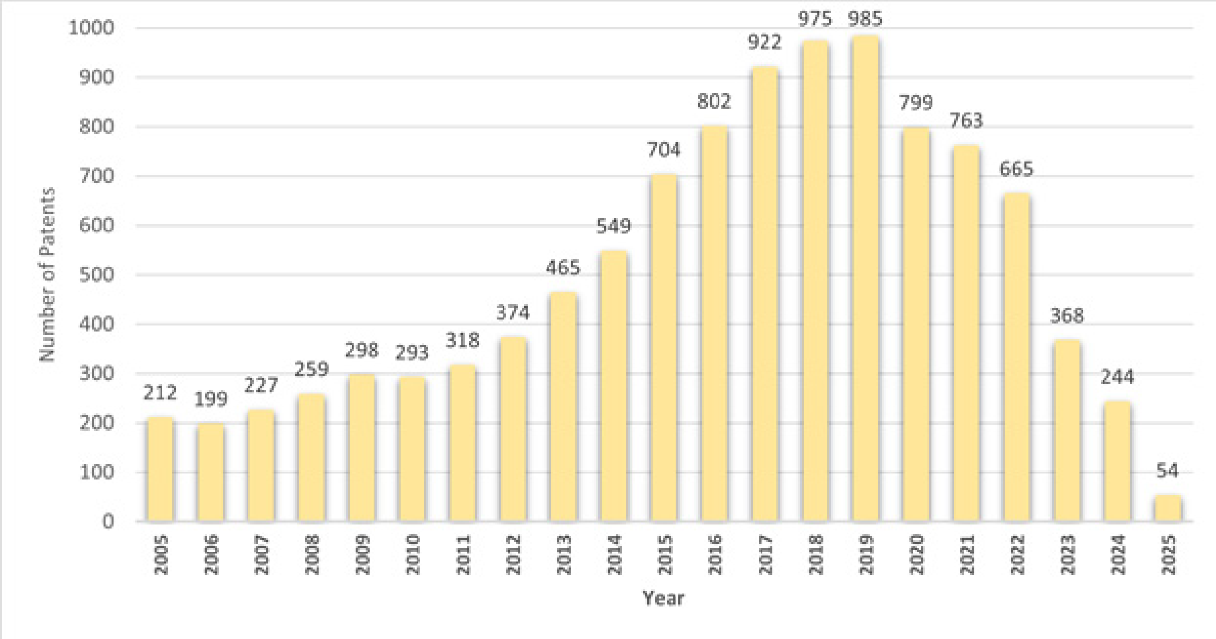


**Figure 1.** Temporal trends of granted patents in regenerative medicine, 2005-2025

Table 1 presents the number of granted patents and their annual growth rates in the field of RM during the period 2005–2025. The results indicate fluctuations in annual patent growth, with the highest growth rate (28.23%) observed in 2015, suggesting a substantial increase in innovation activity in this field. Furthermore, the Compound Annual Growth Rate (CAGR) for the period 2005–2022 was 6.96%, confirming the sustained long-term growth trend in RM patenting. The CAGR was calculated through 2022 because recently granted patent data may be incomplete due to delays in patent examination, granting, and database indexing.

Although negative growth rates were observed in recent years, they should not be interpreted as evidence of an actual decline in innovation activity. Unlike scientific outputs such as research articles, the processes of patent filing, examination, and granting require considerably more time. Since this study focused on granted patents, delays in the patent-granting process may have affected the number of patents recorded in recent years. Moreover, patent data are often indexed in databases with a time lag, meaning that records for the most recent years may not yet be complete. Therefore, the observed decline in the number of granted patents in recent years should be interpreted with caution and should not necessarily indicate a real decline in innovation activity in the field of RM.

**Table 1.** Annual growth rates in RM, 2005–2025

| Year | Number of patents | % Annual growth rate (AGR) |
|---|---|---|
| 2005 | 212 | - |
| 2006 | 199 | - 6.13 |
| 2007 | 227 | 14.07 |
| 2008 | 259 | 14.10 |
| 2009 | 298 | 15.06 |
| 2010 | 293 | - 1.68 |
| 2011 | 318 | 8.53 |
| 2012 | 374 | 17.61 |
| 2013 | 465 | 24.33 |
| 2014 | 549 | 18.06 |
| 2015 | 704 | 28.23 |
| 2016 | 802 | 13.92 |
| 2017 | 922 | 14.96 |
| 2018 | 975 | 5.75 |
| 2019 | 985 | 1.03 |
| 2020 | 799 | - 18.88 |
| 2021 | 763 | - 4.51 |
| 2022 | 665 | - 12.84 |
| 2023 | 368 | - 44.66 |
| 2024 | 244 | - 33.70 |
| 2025 | 54 | - 77.87 |

**Note:** The compound annual growth rate (CAGR) for the study period (2005–2022) was 6.96%

**Geographic Distribution (Country Level)**

The global distribution of patenting activity is shown in Figure 2, revealing a highly concentrated landscape. China accounts for 41.41% of all granted patents, making it the leading contributor, followed by the United States with 31.95%. Together, these two countries represent more than 73% of global RM patenting activity. South Korea ranks third among contributing nations (8.5%), while Germany, Russia, Japan, the United Kingdom, France, Switzerland, and Canada make up a smaller but notable secondary group. As shown in Figure 2, the overall distribution highlights substantial regional disparities and a strong concentration of innovation capacity in East Asia and North America.

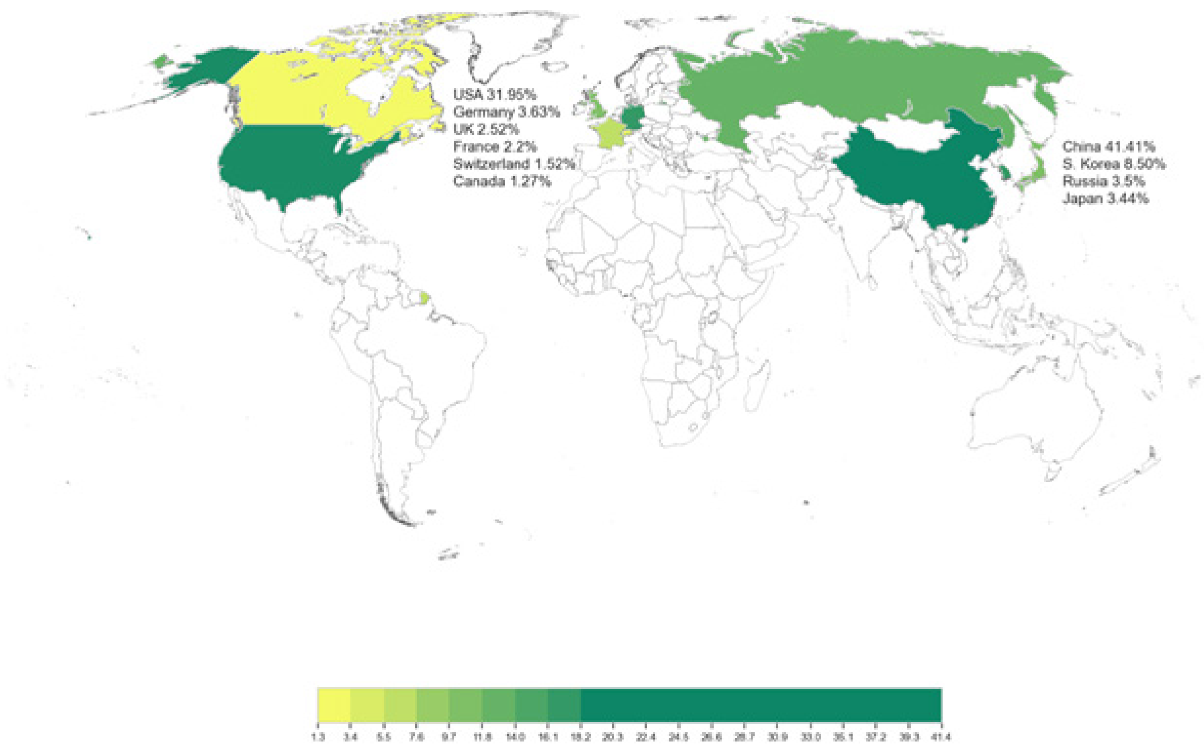


**Figure 2.** Geographical distribution of granted patents in the field of RM

## Technology Analysis

The distribution of the top ten technology domains relevant to RM is presented in Figure 3. Pharmaceuticals constitute the largest share of patenting activity (34%), followed by biotechnology (19%) and medical technology (18%). Together, these three domains represent more than 70% of all identified patents. The remaining technological areas—including other special machines (6%), analysis of biological materials (6%), macromolecular chemistry and polymers (6%), organic fine chemistry (3%), basic materials chemistry (3%), machine tools (3%), and textile and paper machines (2%)—contribute smaller yet functionally significant shares. Overall, this distribution reflects a concentrated technological landscape anchored in core biomedical fields.

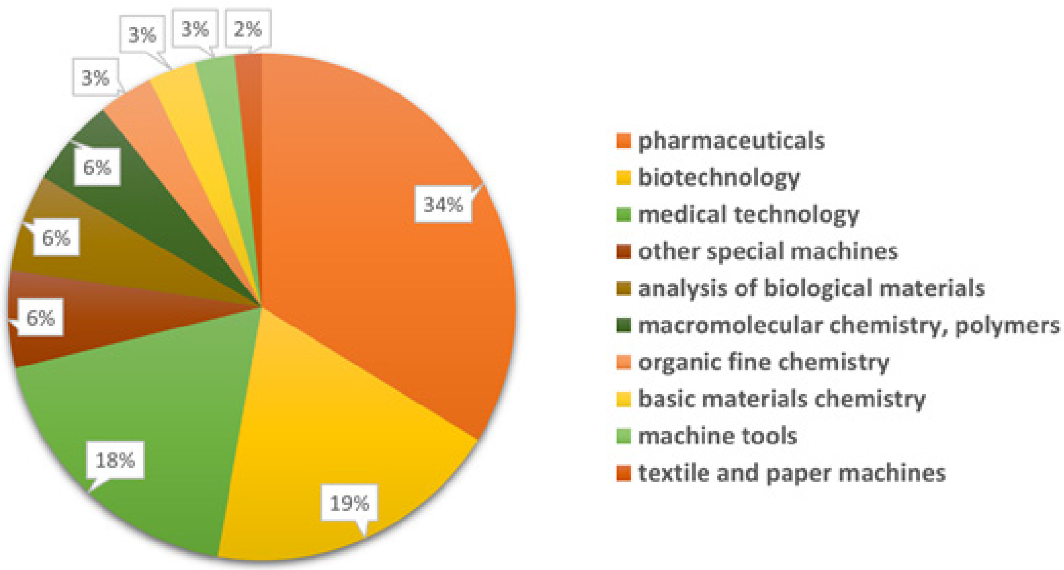


**Figure 3.** Patent share of the top ten technology domains in RM

**Cross Country Distribution of the Top Five Technology**

The cross-country distribution of the five leading technology domains is visualized in Figure 4. The heatmap shows that the United States leads in pharmaceuticals and biotechnology, with substantially higher patent counts than other countries. In contrast, China dominates medical technology, other specialized machines, and macromolecular chemistry and polymers, as indicated by the stronger shading in their corresponding cells. South Korea, Germany, and Japan show moderate but consistent contributions across all five domains. Figure 4 highlights a differentiated global pattern in which technological leadership is divided between biologically oriented innovation, led primarily by the United States, and engineering- and materials-based innovation, led mainly by China.

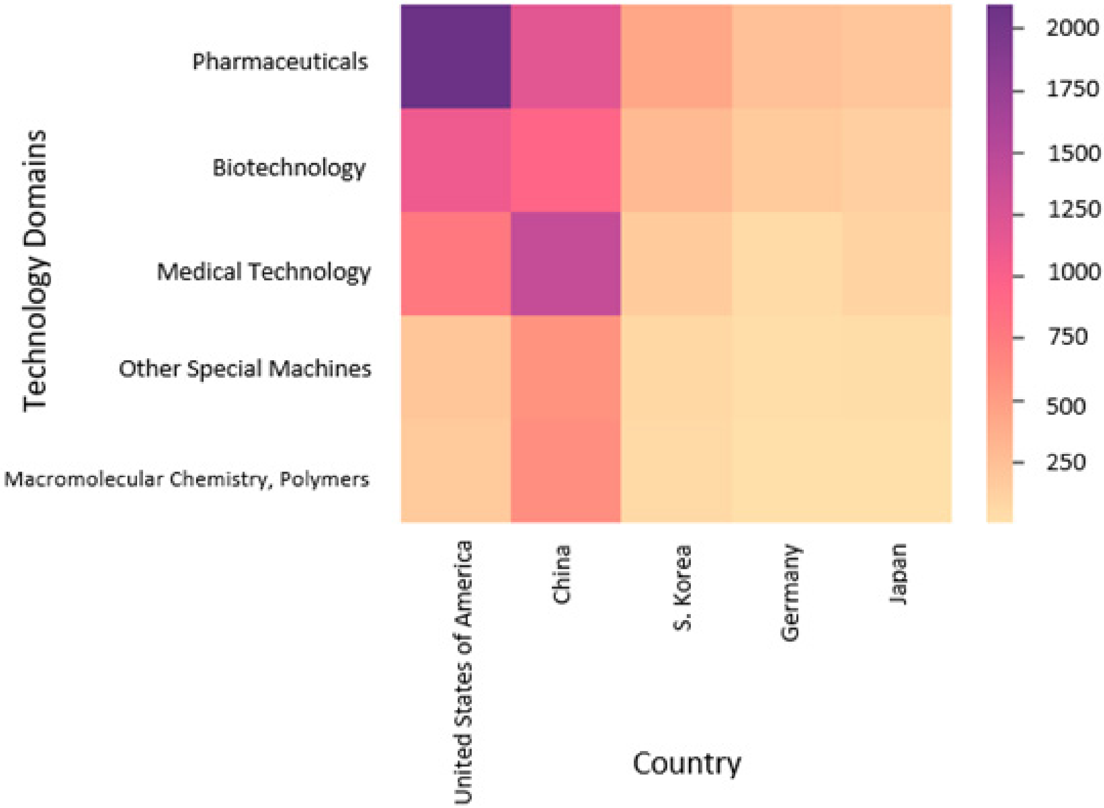


**Figure 4.** Heatmap showing the distribution of granted patents across the top five technology domains in RM for the five-leading patent-producing countries

## Discussion

The results of this study provide an integrated picture of how innovation in RM has developed and become globally structured over the past two decades. Three main patterns emerge: a rapid temporal expansion followed by a plateau, a highly polarized geographic concentration, and a sharply differential technological specialization among leading countries. Taken together, these findings illuminate the maturation of RM from an emerging interdisciplinary domain into a consolidated field of biomedical innovation.

As presented in the results, the patent landscape in RM is defined by a significant inflection point between 2015 and 2020, during which nearly half of all patents were granted, followed by a noticeable stabilization phase post-2019. This non-linear trajectory highlights a transition from an intensive expansion period to a subsequent consolidation of patenting activity.

This developmental trajectory aligns with patterns observed in other high-tech biomedical sectors.

For instance, studies on organoid technologies and gene-editing therapies have documented similar "hype-cycle" dynamics, characterized by an initial surge in patent filings, followed by a plateau as the technologies mature (12, 18). However, the present data reveals a more pronounced deceleration post-2019 compared to the steady exponential growth reported in earlier stem-cell patent analyses (19), suggesting that RM may be moving faster toward industrial standardization than previously anticipated.

The underlying drivers of these fluctuations are multifaceted. The surge between 2015 and 2020 reflects the downstream impact of foundational scientific breakthroughs from the early 2010s—most notably the 2012 Nobel-recognized cellular reprogramming—which finally reached the patent-granting stage after the standard examination lag (20). Furthermore, the implementation of the America Invents Act (AIA) in the US significantly influenced this activity by modifying procedural mechanisms that favored strategic filing. Conversely, the post-2019 slowdown likely signals a market correction or a shift in focus. In this consolidation phase, innovation strategies are pivoting from the acquisition of broad, early-stage intellectual property toward the technical refinement, clinical validation, and optimization of existing platforms—a behavior typical of sectors transitioning from academic research to commercial viability (21).

From a geographic perspective, the strong concentration of patents in China and the United States reflects profound asymmetries in global R&D capacity. China's rapid emergence is consistent with its state driven strategy in biomedical engineering (21). At the same time, the United States' leadership is sustained by its long-standing dominance in life sciences research and by university–industry partnerships. This polarization mirrors broader trends observed in other biomedical domains; for instance, a bibliometric analysis by Zhu et al. (16) identified a similar group of leading economies—including China, the US, Germany, South Korea, and Japan—in the field of organoid technologies, suggesting that RM innovation is concentrated within a stable core of technologically advanced economies.

However, this concentration is not merely a function of R&D capacity; international IP frameworks and jurisdiction-specific regulatory hurdles heavily mediate it. As Zachariades highlights, the leadership of the United States has been significantly facilitated by a flexible patent-eligibility framework that actively encourages private investment in stem cell-related inventions (22). In contrast, the global geography of patenting is further shaped by how different regions manage cross-border IP protection. Komatani (23) emphasizes that navigating this landscape requires the strategic use of global treaties, such as the Patent Cooperation Treaty (PCT) (24), which allows applicants to secure priority across multiple jurisdictions.

Furthermore, the interpretation of these geographic patterns must account for ethical constraints. The regulatory environment in Europe has historically been more restrictive due to ethical constraints on embryonic stem cell research. Komatani (23) notes that patent eligibility in such jurisdictions often hinges on technical workarounds, such as methods for deriving human embryonic stem cell lines without destroying embryos (17). Collectively, these insights suggest that the observed patenting intensity is not solely a reflection of scientific capability but also a direct consequence of tighter moral and legal boundaries that define the patentable space across regions. This convergence of factors explains why innovation in RM remains concentrated within a specific group of nations capable of aligning their scientific output with complex global IP and ethical requirements.

The dataset's technological structure shows a high degree of specialization, with over 70% of patenting activity concentrated in three primary domains: pharmaceuticals, biotechnology, and medical technology. Furthermore, the cross-country analysis reveals a distinct division of innovation labor: the United States leads in biology- and drug-based innovation, while China shows a comparative advantage in engineering- and materials-oriented technologies. Other nations, including South Korea, Germany, and Japan, maintain diversified but supportive roles without achieving the same level of global leadership in these specific sub-fields.

This dominance of biologically grounded platforms is consistent with broader innovation trends in RM. For instance, partnership analyses in biotechnology-driven ecosystems have similarly highlighted that the majority of strategic agreements are centered on gene-based products and early-stage therapeutic development (25). Moreover, studies utilizing USPTO data confirm that mesenchymal stem cells, exosomes, and CAR-T therapies remain the dominant innovation trajectories within the field (26). The observed leadership of the United States in pharmaceuticals and biotechnology also aligns with documented patterns of federal support, in which agencies such as the National Institutes of Health (NIH) have historically prioritized therapeutic and biological research over pure engineering (27).

The underlying reason for this technological concentration is that the commercial and scientific core of RM is still heavily rooted in foundational biological discovery. However, the presence of macromolecular chemistry and polymer science in the data suggests that the field is entering an interdisciplinary phase where progress depends on "convergent technology development." The observed segmentation of competencies between the US (biology-based) and China (engineering-based) implies a structural complementarity. This division suggests that while the US provides the foundational biological intellectual property, China's focus on materials and engineering may be driving the scalability and manufacturing aspects of these technologies. Recognizing these national specializations is crucial, as the future translation of RM into clinical applications will likely require a balance between biological discovery and engineering scalability, facilitated by international partnerships.

The present study has several limitations that should be acknowledged. First, the analysis is based exclusively on data retrieved from the Orbit Intelligence database; therefore, the findings may be influenced by the platform's coverage, indexing policies, and data structure, and patents indexed in other databases are not captured in this study. Second, the study is limited to granted and expired patents, while excluding pending applications. Although this approach ensures a focus on more reliable indicators of technological maturity, it may also omit early-stage or emerging innovations that have not yet reached formal approval. Third, patent data represent only one dimension of innovation. Accordingly, this study does not include other relevant sources of technological activity, such as unpublished industrial research, proprietary developments, or clinical trial outcomes, which may also contribute to the broader innovation landscape in RM. Finally, future research could address these limitations by integrating multiple patent databases, combining patent data with scientific publication and clinical trial datasets, and employing advanced network-based analytical approaches to provide a more comprehensive and multidimensional understanding of innovation dynamics in this field.

## Conclusion

This study demonstrates that RM has undergone substantial technological expansion over the past two decades. The temporal analysis reveals a steady increase in inventive activity, followed by a pronounced surge between 2015 and 2020, during which nearly half of all identified patents were granted. This pattern reflects both the rapid advancement and the early stages of technological consolidation within the field. Geographically, innovation is highly concentrated, with China and the United States together accounting for the majority of global patent output, complemented by notable contributions from Japan, South Korea, and Germany. The analysis of technology domains highlights pharmaceuticals and biotechnology as the dominant drivers of innovation within the RM landscape. Overall, the findings underscore the value of patent based intelligence for monitoring technological trajectories and provide evidence to inform research prioritization, strategic investment, and policy development in this evolving, commercially significant field.

## Declaration

### Acknowledgment

None.

### Conflict of Interest

The authors reported no potential conflict of interest.

### Ethical Statement

The present study was based exclusively on publicly available patent data and did not involve human participants, animal subjects, or any identifiable personal information. Therefore, ethical approval and informed consent were not required. The authors confirm that all ethical principles of scholarly publishing have been observed.

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### Authors' Contribution

Homa Arshadi: Conceptualization, Methodology, Validation, Investigation, Writing – original draft, Writing – review and editing.

Atefeh Nejadebrahim: Conceptualization, Methodology, Validation, Investigation, Writing – original draft, Writing – review & editing.

Mina Avazbeigi: Data curation, Formal analysis, Methodology, Software, Visualization.

### Use of Artificial Intelligence

During the preparation of this work, the authors used ChatGPT to improve the clarity and readability of the manuscript. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the published article.

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**Appendix 1.**
**Search Strategy**

The patent search was conducted using the following keywords related to regenerative medicine technologies in the title, abstract, and claims fields of the Orbit Intelligence database:

"Regenerative medicine" OR "wound healing technologies" OR "tissue engineering" OR "stem cell therapy" OR "organ regeneration" OR "gene therapy" OR "cellular regeneration" OR "cell therapy" OR "biomaterial for tissue repair" OR "biological repair" OR "advanced therapy medicinal products" OR "scaffold based therapies" OR "bioprinting".