The Regenerative Medicine Market

1

Regenerative medicine is a medical field that aims to replace or regenerate human organs and tissue through gene therapy, stem cell technology, and tissue engineering. Many of the recent developments in the field are still in the research and development stage, and for this reason, regenerative medicine is often considered to be on the frontier of modern medicine. In fact it may be another 20 to 30 years before the full potential of regenerative medicine technologies can be utilized. However, the potential applications of regenerative treatments are so promising that the market is quite robust today. In 2016, for example, investors financed approximately $5.22 billion in regenerative medical research.

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There are several reasons why public and private investment in this field is growing. Investors are looking for treatments that are more successful at treating chronic and degenerative diseases—including types of cancer. Gene therapy and other regenerative medical procedures are novel treatments compared to existing technology. For example, in the first-ever gene therapy that is close to being approved by the US Food and Drug Administration (FDA), leukemia is targeted with a patient's own cells, which are genetically altered to attack tumor cells. In addition to combating disease in innovative ways, regenerative medicine also offers a solution to the issue of organ-donor shortages by engineering synthetic organs. As demonstrated in Figure 1, other reasons why the regenerative medicine market is growing today include current advancements in tissue regeneration, nanotechnology, and stem-cell technology.

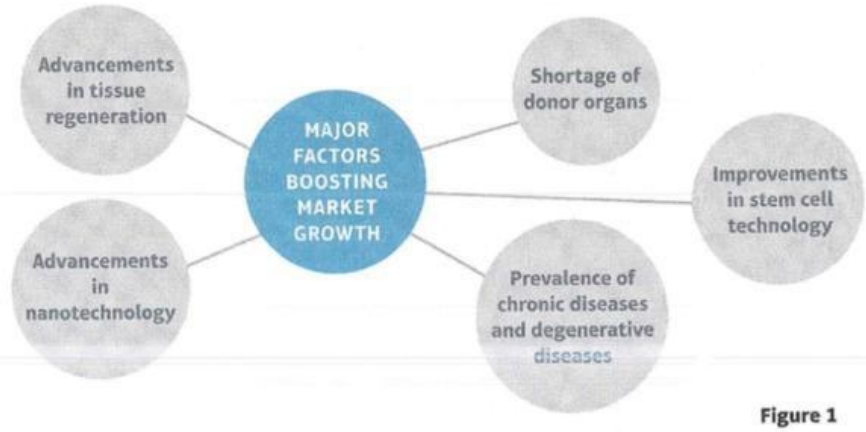


Figure 1

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The major question about regenerative medicine therapies that many doctors and patients ask is when the treatments will be ready for use. First, the therapies must move out of the research stage and into clinical trials, which test treatments on humans. Notably, the number of clinical trials in regenerative medicine rose considerably from 2015 to 2016. Figure 2 shows that in 2015, there were 631 clinical trials underway. That number rose to 804 in 2016, meaning that researchers are moving closer to making certain regenerative treatments a viable option for patients. Phase I trials, which represent the early stages of a drug trial, rose from 192 in 2015 to

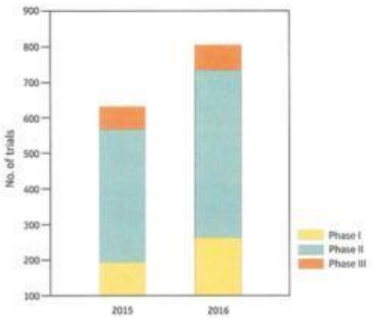


Figure 2: Clinical trials in regenerative medicine

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261 in 2016. Phase II trials rose from 376 in 2015 to 475 in 2016. Finally, Phase III trials, which are also called late-phase trials, rose slightly, from 63 in 2015 to 68 in 2016.

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Most of these trials involve cellular therapies and gene therapies. In 2016, worldwide there were approximately 425 gene-therapy trials and 533 cell-therapy trials. There were also 20 clinical trials in the field of tissue engineering in the same year (see Fig. 3). Some clinical trials had crossover between cell therapy and gene therapy, which is why the total number of clinical trials by type in Figure 3 exceeds the 804 total clinical trials for 2016. The United States is currently the nation with the largest number of clinical trials of all types. For example, researchers found that between 1989 and 2015, the United States was home to 66.81 percent of all gene-therapy clinical trials.

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The United Kingdom had the second highest number during the same period, with 9.45 percent of all gene-therapy trials. Figure 4 demonstrates the distribution of all gene-therapy clinical trials worldwide between 1989 and 2015. In the coming years, more regenerative therapies are likely to be tested and approved.

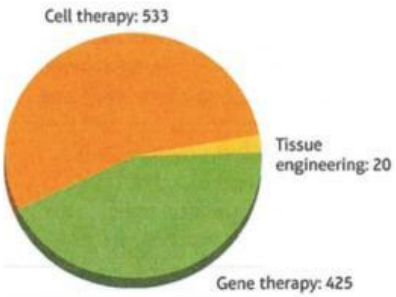


Figure 3: Clinical trials in regenerative medicine by type, 2016

Question 1: What is the primary goal of regenerative medicine?
A) To develop new pharmaceutical drugs for chronic diseases
B) To replace or regenerate human organs and tissue through advanced technologies
C) To improve surgical techniques for organ transplantation
D) To create vaccines for degenerative diseases

Question 2: According to the passage, how long might it take before the full potential of regenerative medicine technologies can be utilized?
A) 5 to 10 years
B) 10 to 15 years
C) 20 to 30 years
D) 40 to 50 years

Question 3: Approximately how much did investors finance in regenerative medical research in 2016?
A) $2.5 billion
B) $3.8 billion
C) $5.22 billion
D) $7.1 billion

Question 4: What innovative approach does the first-ever gene therapy close to FDA approval use to treat leukemia?
A) Synthetic organs that replace damaged bone marrow
B) Nanotechnology that delivers drugs directly to tumor cells

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C) A patient's own cells that are genetically altered to attack tumor cells
D) Stem cells from donors that are modified to fight cancer

Question 5: How many clinical trials in regenerative medicine were underway in 2016?
A) 631
B) 708
C) 804
D) 978

Question 6: Which phase of clinical trials showed the largest numerical increase from 2015 to 2016?
A) Phase I trials
B) Phase II trials
C) Phase III trials
D) All phases increased equally

Question 7: In 2016, which type of therapy had the highest number of clinical trials worldwide?
A) Gene therapy
B) Cell therapy
C) Tissue engineering
D) Nanotechnology therapy

Question 8: Why does the total number of clinical trials by type in Figure 3 exceed the total number of clinical trials for 2016?
A) Some trials were counted twice due to reporting errors
B) International trials were added to domestic trials
C) Some clinical trials had crossover between cell therapy and gene therapy
D) Phase III trials were counted separately from other phases

Question 9: Between 1989 and 2015, what percentage of all gene-therapy clinical trials were conducted in the United States?
A) 45.23 percent
B) 56.47 percent
C) 66.81 percent
D) 75.92 percent

Question 10: Which country had the second highest number of gene-therapy clinical trials between 1989 and 2015?
A) Germany
B) Japan
C) Canada
D) The United Kingdom

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