

Mapping the trends and current global landscape of immunotherapies

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Opportunities and Challenges for the Cellular Immunotherapy Sector: A Global Landscape of Clinical Trials

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Immunotherapies being developed offer new ways to use living cells from the human immune system to target cancerous cells for therapeutic treatments. Examining numerous immunotherapy clinical trials over the past 20 years illustrates several trends in immunotherapy and gives researchers and businesses a better understanding of the current state and future directions that this field may progress.



What questions & challenges are raised?

Development and investment into immunotherapies has greatly grown in recent years because of their potential to harness the power of the human immune system to target and destroy various forms of cancer. Immunotherapies can be based on small molecules, such as drugs; large molecules, such as antibodies and other proteins; or living cells that are part of the immune system. Immune cell treatments differ from other treatments because they involve injecting living cells into a patient. These living cells then actively seek out cancer cells and assist the immune system to destroy them. In their recent publication, Katherine Bonter from Genome Canada Personalized Cancer Immunotherapy Program, Tania Bubela from Simon Fraser University and their colleagues analyse reported clinical trials to establish an overview of what global trends are for cellular immunotherapy treatments. Being the first study of its kind to examine immune cell treatments, the authors shed light on many current trends, such as the total number of trials, where trials are occurring, who is financially supporting trials, what diseases the treatments are for, and even what specific proteins the treatments identify to target cancers.

What insight & direction does this give for research policies?

The numerous CTs identified by Dr Bonter and colleagues show the field of cellular immunotherapy has been growing. Yet, only two treatments have attained FDA approval, one of which was a cancer treatment that ultimately was commercially unsuccessful. This exemplifies the large risks for treatment sponsors even after successful CTs and approval. So how is the field of cellular immunotherapy moving forward? Who are the sponsors? The authors show that public funding and academic institutions dominate clinical testing and play a particularly important role in supporting the risks and costs of studying new disease targets and methods. For example, it's been almost forty years since research first began on 'adoptive cell transfer' (ATC) methods using CAR T-cells. This CAR-T treatment approach has shown extremely promising results and was a just recently approved by the FDA as a therapy called Kymriah for treating a form of leukaemia. The Kymriah CT was sponsored by Novartis, which is the only company of the top 25 global pharmaceutical companies to sponsor a cellular immunotherapy CT. However, the authors' analysis shows an increasing trend in smaller companies sponsoring CTs in North America, East Asia and Europe. The authors' data shows that new methods and targets are being explored, which will certainly help address some of the challenges facing cellular immunotherapies. One such challenge is accurately targeting cancer cells. Cancers arise from malfunctioning normal cells, so immunotherapies might target both cancer cells and healthy cells that 'appear' similar. This can be a serious problem if the body cannot easily replace the healthy cells. Finding these new protein targets is

expensive, slow and usually not supported by businesses at first, as is shown by the authors' data. Public funding and academic research will continue to play a very important role in the growth of cellular immunotherapy. The authors' report discusses many areas of this growing field of research. It also offers insight and a general outlook that should aid sponsors and other stakeholders in building realistic business models and developmental time lines for creating clinically successful cellular immunotherapies. Asia and Europe. The authors' data shows that new methods and targets are being explored, which will certainly help address some of the challenges facing cellular immunotherapies. One such challenge is accurately targeting cancer cells. Cancers arise from malfunctioning normal cells, so immunotherapies might target both cancer cells and healthy cells that 'appear' similar. This can be a serious problem if the body cannot easily replace the healthy cells. Finding these new protein targets is expensive, slow and usually not supported by businesses at first, as is shown by the authors' data. Public funding and academic research will continue to play a very important role in the growth of cellular immunotherapy. The authors' report discusses many areas of this growing field of research. It also offers insight and a general outlook that should aid sponsors and other stakeholders in building realistic business models and developmental time lines for creating clinically successful cellular immunotherapies.

What background and point are discussed?

The study by Dr Bonter and colleagues found a total of 1,579 clinical trials (CTs) examining the safety, tolerability and effectiveness of cellular immunotherapy treatments. Most of the trials examined (1,560 - 98.8%) were started between 1995 and 2015 and over those 20 years the number has steadily grown from fewer than 10 trials in 1995 to over 170 in 2015. Thirty-three different countries have reported cellular immunotherapy trials, with the United States responsible for over half of these (~54%), followed by China (\sim 9.0%), Japan (\sim 8.8%), Netherlands (\sim 3.4%), Germany (\sim 2.6%), and the United Kingdom (\sim 2.5%). The dominance of the US has diminished since 2008 with growing numbers of studies from East Asia and Europe. From 1995 to 2015, the proportion of studies focused on treating solid cancerous tumours and cancers of the blood has remained relatively constant, roughly 50% and 25% respectively. Industry sponsorship of CTs has grown four-fold since 1999, with studies from East Asia most likely to have industry sponsors. However, the majority of CTs, particularly studies examining new disease targets, are publicly funded studies run by academic centres. The largest funder for CTs was the US National Institutes of Health (NIH). The authors also report on other details and trends that are beyond the scope of this summary, such as treatment methods, proteins that treatments target and the statistical preferences of industry sponsors towards CTs using different cell types.