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Translation of cellular therapies for clinical applications

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Cellular therapies offer the potential to treat and possibly cure many life threatening diseases, however there are many issues to be solved for translation of the basic biology to clinical utility. Tissues and organs are complex biological systems and cellular products must be integrated into the existing tissue to maintain not only the function but the integrity of the tissue. Although autologous cells are optimal for therapy, they may be limited due to genetic faults or damage through the disease process. Allogenic cells must contend with immune barriers which could result in rejection or graft versus host disease. The manufactures of the cellular therapy products must be performed in accordance with FDA guidelines and typically require cGMP facilities. The production costs are high and evaluation in clinical trials is expensive. Ideally development of cellular products would be conducted by the pharmaceutical industry however, many of these cellular products lack suitable patent protection and therefore industry has not been as active as needed. Alternate models may need to be explored by academic programs such as developing cellular products as standard of care through small phase II studies. In summary there are many hurdles to be overcome before cellular therapies become routinely used for clinical applications but the potential of these products will fill critical needs in clinical care.

Biography

Ian McNiece is a Professor of Medicine at The University of Texas MD Anderson Cancer Center in Houston and Director of the Cellular Therapy Laboratories (CTL). The CTL processes stem cell products for over 800 transplants a year and supports more than 10 phase I through phase 3 clinical trials of cellular and immunotherapies. His research has focused on stem cell biology and the control of proliferation and differentiation of stem cells by growth factors. His work has studied aspects of stem cells in clinical marrow and stem cell transplantation leading to clinical trials in mobilization and *ex vivo* expansion.

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