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**TISSUE PRESERVATION, LIFE CARE AND BIOBANKING** 

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## Cryopreserved or fresh therapeutic mesenchymal stromal cells: Past, present, and future

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**B**ensure that new cryobanked products and applications are fit for purpose, which is particularly important for novel cryobanked cellular therapeutics. Mesenchymal stem cell (MSC)-like advanced therapy medicinal products (ATMPs) in hundreds of clinical trials, to efficacy evaluation so far. Results from first phase III clinical studies indicate that the implementation of 1st generation MSC-like ATMPs is hampered by and suboptimal therapeutic efficacy. Failure analysis to understand the encouraging preclinical data and at times modest clinical performance is ongoing. This is hampered by MSC's highly complex mechanisms of action, involving multiple immunomodulatory and regenerative mediators and pathways. Thus, major efforts to refine potency assessment are currently underway. Great uncertainty exists considering the predominant use of log-phase culture-derived "freshly-harvested" cells in favored use of cryobanked "freeze-thawed" cells in the clinical setting. Another major confounder is the frequent use of minimal-expanded MSCs in academic trials versus highly expanded MSCs in many industry-sponsored studies. An explosion of literature comparing the efficacy of fresh and frozen cells underlines the relevance of this topic. We appear to witness a translational bottleneck in up-scaling preclinical assessment to clinical operations. Development of optimized next-generation MSC-like ATMPs may allow for harnessing MSCs full therapeutic potential in the future.

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