



**Title: Cell-based Therapies - Through the Looking-Glass**

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**Abstract:**

Regardless of having several approved ATMPs and about 5,000 registered clinical trials of cell containing products (excluding T cells), our knowledge about the principles of cell-based therapies in regenerative medicine is still very limited. The fundamental questions still remains: Do cells survive after being delivered? For how long? Are the cells, with multipotency confirmed in vitro, still multipotent in host tissues? Which is the predominant therapeutic mode of action: delivery of components to restore tissue in situ or providing trophic and/or immunomodulatory agents? It is not surprising, as we look at it. Unlike traditional medicines, the seemingly identical ATMPs can vary radically in terms of cell number, detailed manner and number of applications, medium used for cell delivery, details of in vitro manipulations prior to application - just to mention the most important variables that characterize each individual treatment. At the same time cell-based therapies are extremely demanding in terms of scientific, technical, regulatory and financial challenges, which explains much pressure put on the breakthrough success and the establishment of new directions. A critical review of those issues, based on the available data and our own experience, shows that the last two decades have not been a waste of time, and the further directions toward development of effective cell-based therapies can be identified.

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