

## **Stem Cells: replacement therapy**

Giulio Cossu

Division of Regenerative Medicine, San Raffaele Scientific Institute

These years have witnessed extraordinary results of stem cell transplantation for the therapy of previously incurable diseases such as congenital immune deficiencies or epidermolysis bullosa (Mavilio et al. 2006; Aiuti et al., 2009). For many other diseases, trials are imminent and results will be available in the next future. Despite the excitement for providing new therapies for otherwise incurable diseases, we all face a number of problems and risks. The International Society for Stem Cell Research recently published Guidelines for Clinical Translation of Stem Cell Research ( <http://www.isscr.org> ) in order to advise scientists, clinicians and patients on the necessary steps to be undertaken in order to start clinical experimentation with stem cells with minimal risks and maximal chance of success (Hyun et al., 2008).

This rapidly changing scenario unfortunately offers a fertile ground for the explosive proliferation of private clinics all over the world that promise therapies for incurable diseases and are the target of "stem cell tourism". Warning against these treatments by academics will have little impact on those who are desperate and who see a disease progress daily, taking more and more of their own life or that of their loved ones. Although criteria to distinguish between official Institutions and private clinics are obvious to the experts, they may not be so obvious for patients or journalists and the possibility exists that soon the idea that stem cells are a tricky and money-making business may seriously undermine the whole development of the field.

Therefore the stem cell research community is now confronted with this thorny dilemma: making rules more and more rigorous will insure safety but delay progress and raise costs to unaffordable levels; loosening these rules will open to field to private, uncontrolled experimentation that may be deleterious for patients. Finding a balance between these two extremes will be the challenge of the next decade.

Aiuti et al. (2009) *New Engl J Med* 360:447-458.

Hyun et al. (2008) *Cell Stem Cell* 3:607-609.

Mavilio et al. (2006) *Nature Med* 12:1397-402.