

# Cardiac cell therapy: bench or bedside?

On behalf of the Steering Committee of the National Heart, Lung, and Blood Institute Cardiovascular Cell Therapy Research Network

An Editorial published in this journal in early 2007 addressed the status of cardiac cell therapy. In this article, Nadal-Ginard and Fuster suggest that the field is at a 'crossroads' and recommend a moratorium be placed on new clinical trials (Nadal-Ginard B and Fuster V [2007] *Nat Clin Pract Cardiovasc Med* 4: 1). A reason given for the moratorium was that results of therapy could not be evaluated because there was no identifiable therapeutic agent, mechanism of action, or efficacious dose for a putative intervention. The cell type or types and the administration method used were identified as the most important issues that needed addressing before further trials were undertaken.

The uncertainty surrounding this growing field, the compelling clinical need, the supportive preclinical data and the promising early clinical experience prompted the National Heart, Lung, and Blood Institute (NHLBI) to establish the Cardiovascular Cell Therapy Research Network (CCTRN; a full list of contributors is provided in Supplementary List 1 online). The goal of the CCTRN is to accelerate research into the use of cell-based therapies in the management of cardiovascular diseases. The CCTRN is charged by the NHLBI to perform early phase I and II clinical investigations that will help to identify optimum cell-therapy techniques for improving ventricular structure and function. Established in January 2007, the CCTRN expects to begin clinical trials in the latter half of this year.

On behalf of the CCTRN and its investigators, we would like to answer the question of whether the future of cell-based therapies lies at the bench or the bedside. The answer is both—simultaneously. Clinical and basic science researchers should unite in their efforts to meet the challenges ahead. Stem cells are one of the most complex therapeutic agents ever considered for use in clinical medicine. As

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*A full list of members of the Steering Committee of the National Heart, Lung, and Blood Institute Cardiovascular Cell Therapy Research Network is provided in Supplementary List 1 online.*

#### Competing interests

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such, initial clinical studies conducted by the CCTRN will be designed to provide as much mechanistic insight into cell-based therapy as possible.

That we have only a partial understanding of many of the small-molecule pharmacologic therapeutic agents commonly used in clinical practice is a humbling thought. One must remember that only after decades of clinical use was aspirin recognized as an aid in reducing fatalities after myocardial infarction and a more precise understanding of aspirin's mechanism of action was established. We believe it would be naive to assume that we will understand cells as therapeutic agents completely from the onset of their use; however, it is also naive to believe that preclinical studies could determine precisely the effects of cell delivery in our complex patients. Acceptance of the current limitations of our knowledge should not halt efforts to harness this knowledge and to ascertain how it can be used in patients with unmet clinical needs.

Cardiovascular cell therapy is not at a 'crossroads'. As soon as possible, with the support of the NHLBI and the FDA, and because of the clinical safety observed in early human trials, we must find the best and safest stem cell type or types with which to treat our patients—patients with extensive coronary heart disease, heart failure, refractory angina, or claudication for whom there are no other therapeutic options, those who have had cerebrovascular accidents, and those with congenital heart disease. Stem cell therapies can be used in all of these areas. We support a joint basic and translational effort to make these goals a reality—as soon as possible.

**Supplementary information** in the form of a list of contributors is available on the *Nature Clinical Practice Cardiovascular Medicine* website.