

Mapping the Road to the Clinical Translation of Stem Cells

The ISSCR has convened a multinational task force to establish international guidelines for the clinical translation of stem cells and their direct derivatives. The ISSCR Task Force on the Clinical Translation of Stem Cells will define the scientific, clinical, regulatory, ethical, and societal issues that must be addressed to ensure that basic stem cell research is responsibly transitioned into appropriate clinical applications for treating patients.

Stem cell research in all forms is proceeding at an exhilarating pace around the world and holds great long-term promise for the amelioration of currently intractable diseases and conditions. So far, stem cell therapy has only been established as a clinical standard of care for diseases of the blood system. However, there are a growing number of centers throughout the world

that are testing stem cell interventions and some that are claiming to offer stem cell treatments for a variety of conditions without clear evidence of safety or efficacy. In some cases, large sums of money are charged. For the successful application of novel stem cell-based approaches, it will be necessary to define the scientific and clinical advances, as well as the associated regulatory,

Table 1. Members of the ISSCR Task Force on the Clinical Translation of Stem Cells

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Ephrat Levy-Lahad, MD	Shaare Zedek Medical Center, Israel
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Bernard Lo, MD	University of California San Francisco, USA
Dan Marshak, PhD	PerkinElmer Inc., USA
Angela McNab, BA (hons), MA	Department of Health, UK
Megan Munsie, PhD	Australian Stem Cell Centre, Australia
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ISSCR: Committee Forum

ethical, and societal issues, that need to be addressed in order to deliver treatments safely, effectively, and fairly. Stem cell application without such a solid basis not only risks the safety of the patients but may also lead to major delays in the development of clinically useful therapies.

To date, there exists no comprehensive road map to help guide the international stem cell research community, clinicians, industry, patient organizations, and other stakeholders who are committed to advancing the development of stem cell-based therapies. Now more than ever, a commonly shared set of professional guidelines is necessary to ensure that progress in basic stem cell research is responsibly transitioned into appropriate clinical applications for treating patients.

To meet this need, the ISSCR has convened a multinational task force to develop international guidelines for the clinical translation of stem cells and their direct derivatives for human therapy. The ISSCR Task Force on the Clinical Translation of Stem Cells is comprised of leading researchers, clinicians, ethicists, and regulatory officials from 13 countries, each of whom bring to the discussions their unique backgrounds and experiences (Table 1). Particular strength is brought by individuals with prior experience in trials of gene therapy and other innovative clinical therapies, expertise in preclinical animal models, extensive experience in the regulatory aspects of translational medicine, and knowledge of the ethical and policy issues pertinent to the implementation of new therapy. The task force, cochaired by Drs. Olle Lindvall and Insoo Hyun, will address the wide range of scientific, clinical, societal, regulatory, and ethical issues pertinent to the development of stem cell-based therapies through four working groups: the Quality Control and Manufacturing Subcommittee, chaired by Dr. Mahendra Rao; the Preclinical Testing Subcommittee, chaired by Dr. Giulio Cossu; the Clinical Trials Subcommittee, headed by Dr. Ira Fox; and the Social Justice Subcommittee, chaired by Dr. Laurie Zoloth.

The ISSCR Task Force convened as a group for the first time in November 2007 and will work diligently over the course of 2008 via international conference calls and face-to-face meetings. The task force plans to release a draft of their guidelines and recommendations for public comment in association with

the 6th ISSCR Annual Meeting in Philadelphia, June 11–14, 2008. Following a solicitation of comment, the task force will then produce a final draft of the guidelines by the end of the year. Throughout the entire process, we invite those interested to visit the ISSCR website for more information or with suggestions and comments (http://www.isscr.org/clinical_trans).

We thank the members of the task force and other advisors who are volunteering their time, energy, and experience to the development of this important set of guiding principles.

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