

2. Stem Cell Therapeutic Outcomes Database (SCTOD) [table of contents](#)

A component of the C.W. Bill Young Cell Transplantation Program

In December 2005, the Congress of the United States of America authorized legislation of the C. W. Bill Young Cell Transplantation Program (**the Program**) as a new structure to support unrelated donor transplantation in the United States. The Program continues the adult unrelated donor registry, but places a new focus on umbilical cord blood cells for use in transplantation and cellular therapy. The five key components of the Program are:

- National Cord Blood Inventory (**NCBI**) to collect high quality cord blood units (**CBU**)
- Bone Marrow Coordinating Center (**BMCC**) to manage the adult unrelated donor registry
- Cord Blood Coordinating Center (**CBCC**) to manage the NCBI search and distribution of CBU
- Office of Patient Advocacy/Single Point of Access for health care professionals and transplant recipients
- Stem Cell Therapeutic Outcomes Database (**SCTOD**) to collect outcomes data

Implementation of this Program will present new challenges and opportunities for the Hematopoietic Stem Cell Transplantation (**HSCT**) community. Important aspects of the Program are: development of new systems to collect HSCT data electronically, enhanced efforts to develop a standard dataset of HSCT data, new requirements for United States centers to report outcomes data for all allogeneic transplantations, development of a related donor-recipient research sample repository, systems to make more data publicly available, broadened reporting of United States transplant center-specific survival rates, and data collection on uses of stem cells for new therapeutic applications.

Working together, the NMDP and the CIBMTR submitted the winning proposal to administer the SCTOD. Data for the SCTOD component of the Program are collected for all recipients of stem cell therapeutic products (including bone marrow, cord blood, or other such products) from related or unrelated donors where either the donation or the transplant occurs within the United States. The CIBMTR, as recipient of the SCTOD Contract, is responsible for the administration of this activity and the collection and analysis of the data.

In order to minimize the burden of data collection and assure that the most relevant data are collected, the CIBMTR in collaboration with the United States authorities, the American Society of Blood and Marrow Transplantation (**ASBMT**), the European Blood and Marrow Transplant Group (**EBMT**), the Foundation for Accreditation of Cellular Therapy, the World Marrow Donor

Association, cord blood banks and other organizations in the international HSCT community have arrived at a consensus on a reasonable set of common data elements to be collected for all transplant recipients. Both the Transplant Essential Data (**TED**) form (corresponding to the EBMT Med-A form) and the Comprehensive Report Forms were revised to contain these changes and will serve as the tools for collecting HSCT data. The CIBMTR and the NMDP have developed an electronic data collection system (FormsNet™2, for more information see [section 8](#)) to collect these data under the contract.

Effective December 3, 2007 the CIBMTR implemented the revised data collection forms and the FormsNet™2 application for electronic data collection. These tools are used to collect data for all aspects of the CIBMTR, including fulfilling the obligations of the SCTOD.

Recipient data are considered part of the SCTOD if they meet one of the following criteria:

- HSCT occurs at a United States transplant center
- Stem cell collection is performed within the United States
- Cord blood unit is obtained from a cord blood bank within the United States

Recipient data are not considered part of the SCTOD if they meet one of the following criteria:

- Recipient receives an autologous HSCT (see [section 4](#))
 - HSCT does not occur in the United States and the stem cell donor resides outside of the United States
 - Cord blood unit is obtained from a cord blood bank outside of the United States and the transplant occurs outside of the United States

More information about the SCTOD and the C.W. Bill Young Cell Transplantation Program can be found on the CIBMTR website at:

<http://www.cibmtr.org/DataManagement/CenterMembership/SCTODReqs/index.html>