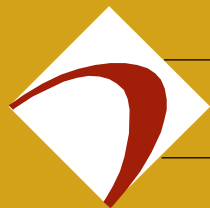


Center for International Blood and Marrow Transplant Research

*Sharing knowledge.....
.....Sharing hope*



CIBMTRTM

CENTER FOR INTERNATIONAL BLOOD
& MARROW TRANSPLANT RESEARCH

The CIBMTR Grew Out of Two Important Collaborative Efforts in BMT

- ® International Bone Marrow Transplant Registry (IBMTR)
- ® National Marrow Donor Program (NMDP)

IBMTR

- ① Voluntary outcomes registry established in 1970
 - 2 years after the first successful HCTs
 - At a time when there were ~ 12 transplant centers, < 50 transplants a year worldwide
- ① Maintained a database of clinical information on recipients of autologous and allogeneic hematopoietic stem cell transplants in ~450 centers in 47 countries
- ① Provided scientific and statistical support for analyzing those data



NMDP

- ④ 1986 – U.S. government appropriated funds to establish the National Bone Marrow Donor Registry (Donor Panel)
- ④ 1988 – U.S. Organ Transplant Amendments Act – mandated collecting outcome data (Recipient Registry); also collects donor outcomes
- ④ ~150 transplant centers and 90 donor centers
- ④ Repository with matched recipient/donor blood samples

CENTER FOR INTERNATIONAL BLOOD AND MARROW TRANSPLANT RESEARCH

- ® Established July 2004
- ® A research collaboration between the International Bone Marrow Transplant Registry and the National Marrow Donor Program to support clinical research in BMT & related fields
 - All of the former IBMTR
 - Research Operations Department of NMDP



NMDP

**NMDP
Research
Operations**

IBMTR

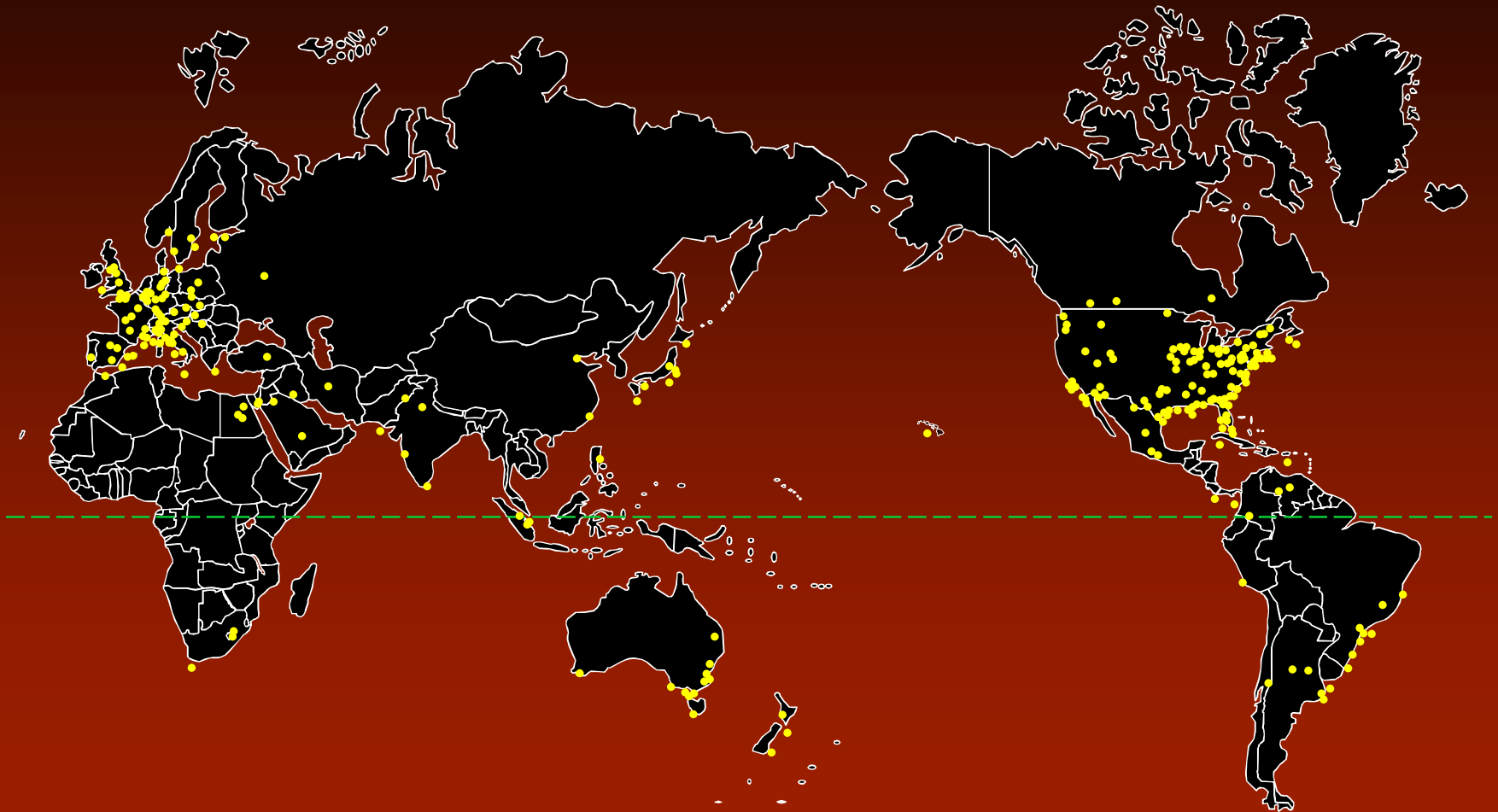
**Medical
College of
Wisconsin**

NMDP

CIBMTR

**Medical
College of
Wisconsin**

CIBMTR, 2009

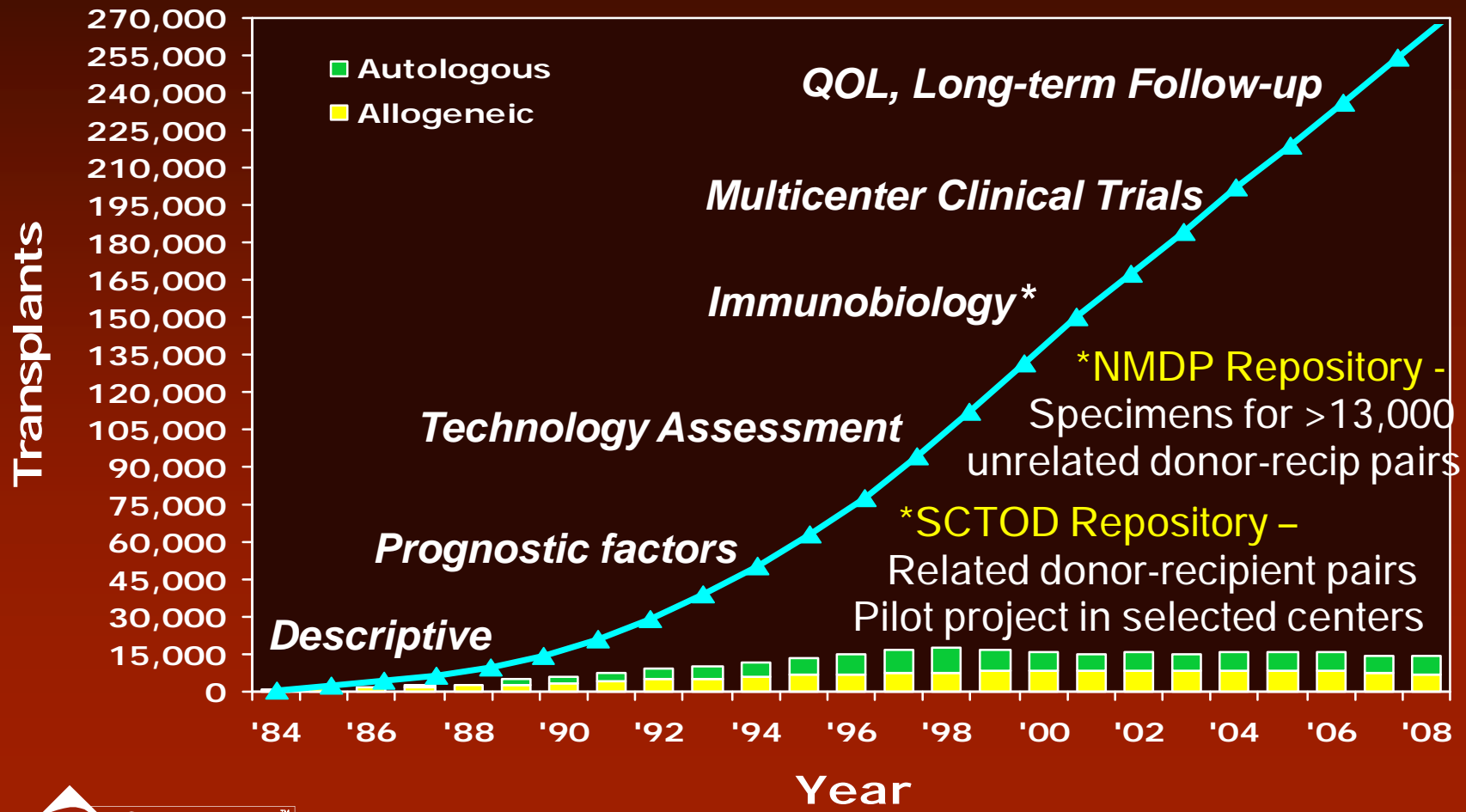


135 staff including, 6 PhD statisticians, 14 MS statisticians, 11 MD-MS faculty;
Active program of statistical methodology research specifically focused on
transplant outcomes in addition to supporting clinical studies

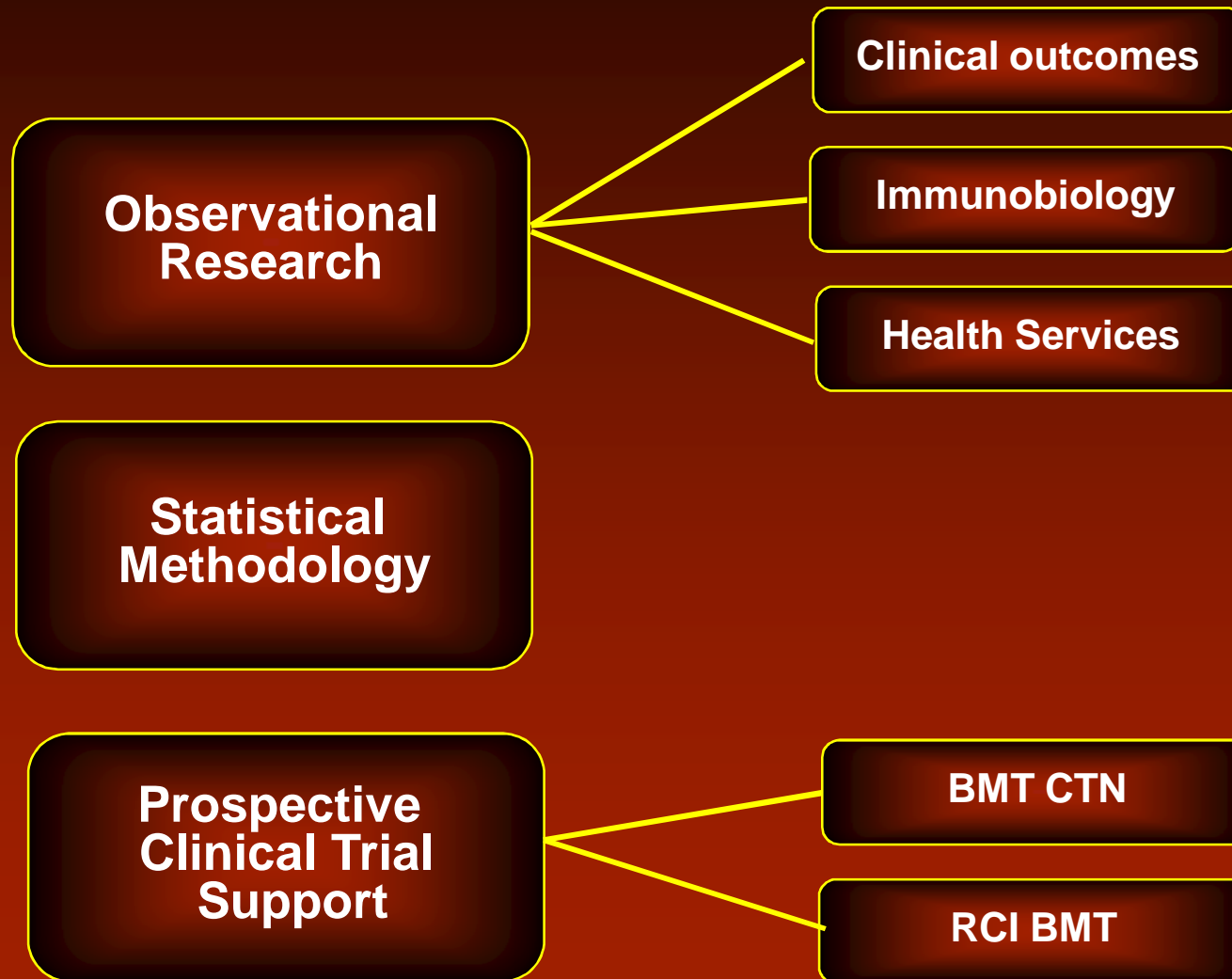
CIBMTR

270,000 Cases Registered, 1984-2008

450 Publications



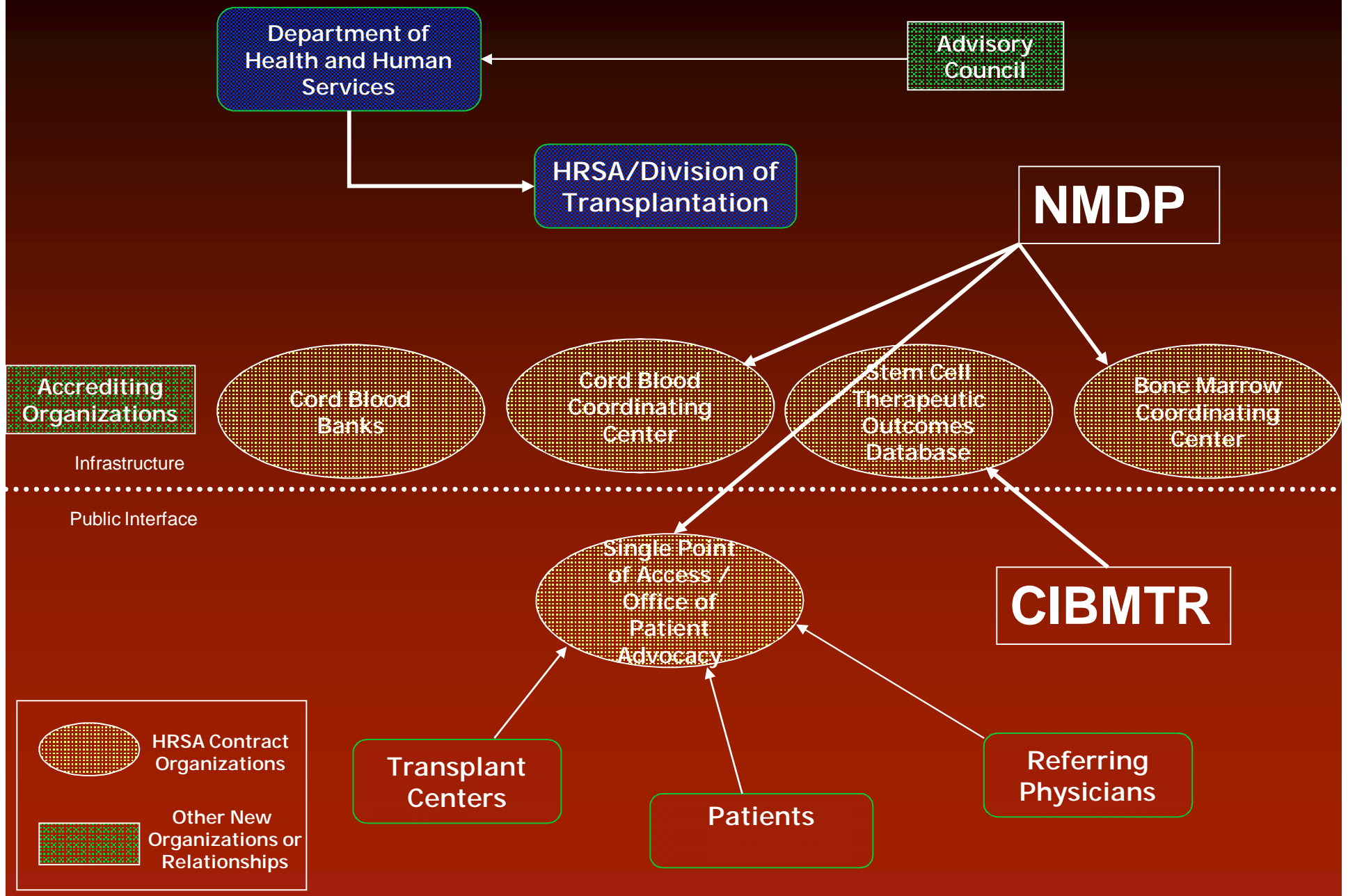
CIBMTR SCIENTIFIC ACTIVITIES



CW Bill Young Cell Transplantation Program

- ® Established by legislation passed in 2005
- ® Successor to National Bone Marrow Donor Registry (contract held by NMDP since 1987)
- ® 5 components:
 - Bone Marrow Coordinating Center
 - Cord Blood Coordinating Center
 - Single Point of Access/Office of Patient Advocacy
 - Cord Blood Banks
 - **Stem Cell Therapeutic Outcomes Database**

Structure of the C.W. Bill Young Cell Transplantation Program



Under the Contract, SCTOD will-

® **Collect data (and specimens)**

- *ALL* allogeneic hematopoietic cell transplants (HCTs) with a recipient or donor from the U.S.
- Related donor-recipient repository
- Other cellular therapies
- Quality of life data
- Secure, efficient electronic data capture system

® **Analyze data**

- Center-specific outcomes for U.S. transplant centers
- Perform analyses of optimal size for the adult donor registry and cord blood unit inventory
- Conduct and support other research using the data collected under the contract

® **Disseminate data**

- Within the Program
- To the scientific and medical community
- To patients, families and the public

Data Collected

® TED-level data

- All allogeneic US HCT recipients
- All autologous HCT recip in US w consent or "center agreement"
- Approved by OMB for SCTOD
- Includes basic demographic, comorbid, HLA, disease, transplant, and outcome data
- Time to complete 30 – 120 min

TED-level INSTRUMENTS

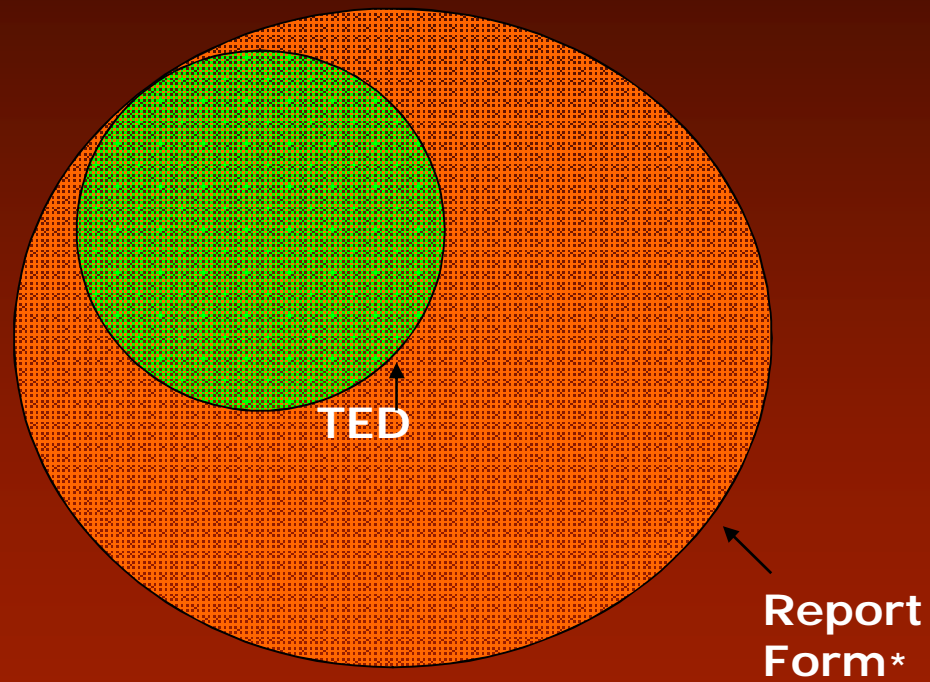
- ® Unique ID
- ® Pre-TED
- ® Post-TED
- ® Death Form
- ® HLA form
- ® Infectious Disease Marker
- ® Infusion form
- ® Timeline: Pre, 100 days, 6 mos, 1 year and annually
 - Overdue 30-60 +days after due

Data Collected

® Comprehensive Report Form

- Randomized selection based on TED level data
- Detailed demographic, disease, transplant and outcomes data
- Typically used for research studies
- Completed at pre-HCT, 100 d, 6 mos, 1 year and annually
 - Overdue 30 – 60 + days after due
- Generally 6-8 hours to complete

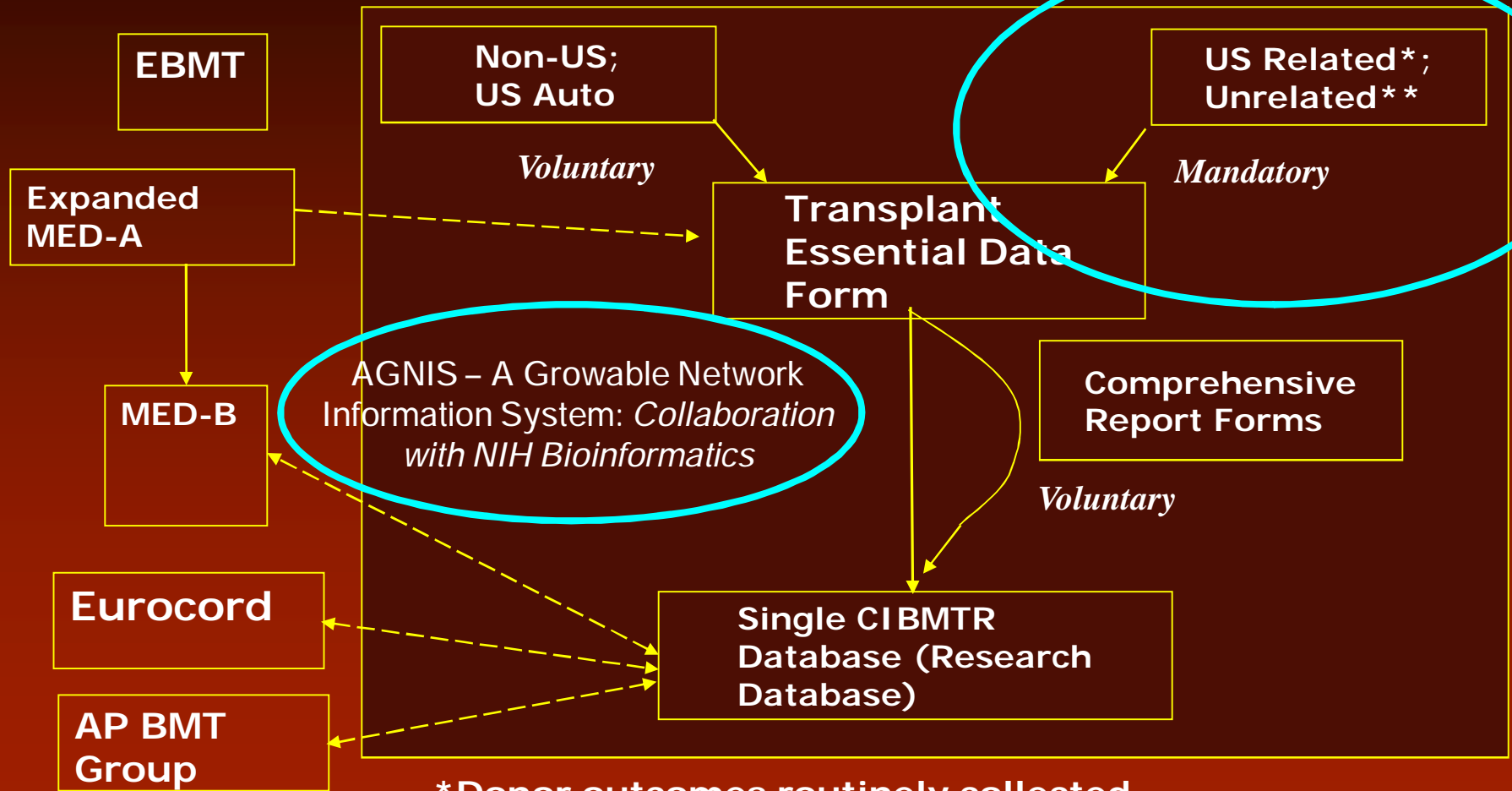
DATA COLLECTION FOR CIBMTR



* Harmonized form replacing NMDP and IBMTR Report Forms

Current/Future Data Flow

SCTOD



* Donor outcomes routinely collected

** Donor outcomes to be collected on subset



What is NOT collected !

- Ⓜ Every Grade 3-5 AE
 - Limited AE collected, not real time
- Ⓜ Detailed infection data
- Ⓜ Details of graft processing
- Ⓜ Detailed additive data
 - Manufacturer, expiration date, lot number, etc

Infusion form example

14. Were anticoagulants added to the product during collection?

1 yes →
2 no

Specify anticoagulant(s):

15. Acid citrate dextrose (ACD)
1 yes
2 no

16. Citrate phosphate dextrose (CPD)
1 yes
2 no

17. Heparin
1 yes
2 no

18. Other anticoagulant
1 yes → 19. Specify other anticoagulant: _____
2 no

Systems to Handle Data

® Inputs

- Paper forms (< 10%)
- Electronic
 - Forms Net 2.0
 - « Direct web-based data entry
 - AGNIS automated data

® Outputs

- Direct printing from Forms Net
- Electronic output of data file
- AGNIS

ROLE OF OBSERVATIONAL DATABASE IN CLINICAL RESEARCH

- ® Analyze trends
- ® Descriptive studies
- ® Identify factors associated with outcome
 - Clinical
 - Center-specific
 - Socioeconomic
 - Biologic/genomic
- ® Assess treatments / strategies
 - Donor selection
- ® Study late effects
- ® Analyze access / utilization
- ® Design / Interpret / Facilitate clinical trials

Limitations of Observational Data Collection

- ① Prospective vs real-time
 - Data collection
 - Interval-based reporting
- ① Focused on outcomes and research, not surveillance and adverse events
- ① Data elements relevant to broad picture
- ① Limited resources for data collection and submission

Questions ?

® Data collection instruments

- www.cibmtr.org/DATA/Data_Mgmt_Forms/index.html

® AGNIS

- www.agnis.net

® FormsNet 2.0

- www.cibmt.org/DATA/data_idx