Should we talk about this or this or ............
Update on Forms Revision

**Forms Revised**

- 2450, 2455, 2100, 2900, and 2814

**Form Changes**

- CRF follow-up forms 2100, 2200, and 2300 are being combined
- TED forms 2450 and 2455 are being combined
- DCI data will now be collected using the new cellular therapy forms, rather than on the HCT follow-up forms

**Tentative Release**

- Summer 2016
Cellular Therapy Registry

- Development led by Marcelo C Pasquini, MD, MS
- Formed a task force
- Objectives of CIBMTR Cellular Therapy Initiative
  - To study uses of cellular products for indications other than hematopoietic replacement or recovery.
  - To provide an infrastructure to allow long-term follow-up of patients treated with cellular therapy
Cellular Therapy Registry Forum
# Cellular Therapy Registry Forum Topics (Oct. 2015)

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<td>- Third Party CTLs</td>
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<td>- Other Targets</td>
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<td>- Cellular Therapy Registry model</td>
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Cellular Therapy Initiative Objectives

1. Build upon the existing infrastructure to develop a cellular therapy registry for research purposes.

2. Tool for long term follow up for cell therapy trials (centers, biotech, regulatory).

3. Increase center participation in this initiative.
Model for the Cellular Therapy Registry

Cellular Therapy

Pre-CTED

Post CTED

Future

Comprehensive Data

CRF

Form 2804/2814

Unique ID Assignment

Hematopoietic Cell Transplantation

Pre-TED

Post-TED

Comprehensive Data

Basic Level Of Data Collection

CRF

CIBMTR

CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

TRAINING & DEVELOPMENT | 8
Cellular Therapy Scenarios

Several scenarios for which we need to collect data

- Cellular therapy followed by HCT (e.g. bridge to HCT)
- Cellular therapy to cellular therapy (new indication)
- Co-infusions: HCT plus cellular therapy
- HCT followed by cellular therapy (e.g. DCI)
- Cellular therapy only

- Regenerative medicine
- CAR T-cells
- CTL for infection

Required

Optional
Cellular Therapy Forms

Revised Form
- 4000: Cellular Therapy Essential Data Pre-Infusion Form
  - Revised to collect only pre-infusion data

New Forms
- 4100: Cellular Therapy Essential Data Follow-Up Form
  - New cellular therapy follow-up form
- 4006 Cellular Therapy Infusion Form
  - Collects data on cellular therapy product infusion

Tentative Release
- Summer 2016
Follow-up on Cellular Therapy Patients

• Follow up will vary according to the type and indication of cellular therapy:
  – Genetic modified cells for any indication
  – Unmanipulated Donor lymphocyte infusion after HCT for treatment of infection
  – MSC infusions for treatment of GVHD
  – Third party CTLs

• Example: FDA mandates 15 year follow up after the infusion of genetic modified cells.
Proprietary Data and Cellular Therapy Registry

- Projects under IND/IDE or pharmaceutical cell products
- Data collection will be the same.
- Establish embargo plan that would control release of outcome data after infusion of a particular product.
- These plans will be protocol or project specific.
Cellular Therapy Registry – Next Steps

- Prioritize certain indications
  - Malignancies (ALL, CLL and others)
  - Infections (Viral infections)
- Prioritize certain products
  - Genetically modified cells
    - Chimeric antigen receptors (CARs) for malignancy
  - Multi-virus T-cells for treatment of infection
- CRF level forms are under development
- Harmonization with EBMT
- Develop a protocol for collection of long term follow up data for genetic modified cells.
Radiation Injury Treatment Network (RITN)

2016 RITN Exercise

- Minimum of 10 centers participate
- Complete RITN forms through 100 days on 3 patients, using test data
- This activity will count towards RITN 2016 Exercise requirement
- Exercise tentatively scheduled for June 2016

If you are a RITN center and would like to volunteer for this exercise, contact RITN@nmdp.org or www.ritn.net
NMDP Analytics

• Additional link on your connect.nmdp page
• The link was made available as part of the TDM (tiered donor management) rollout
• It was made available to anyone who uses the connect site
• It is not part of FormsNet
Attachment Feature in FormsNet3

• Form 2800 (Log of Appended Documents) does not need to be submitted for attachments
Attachment Feature in FormsNet3
## Attachment Feature in FormsNet3

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Attachment Feature in FormsNet3
Attachment Feature in FormsNet3

- All identifying information on the document must be removed or obscured prior to attaching:
  - Patient name
  - Date of birth (DOB)
  - Social security number
  - Address

- If an attached document has identifying information, it will be deleted.
- Need to reattach the document
Attachment Feature in FormsNet3

- CRID clearly located on each page of the document
- At this time only pdf. documents can be attached and viewed
- Do not attach error corrections, they will not be keyed if they are attached to a form
Query Management & Override Tools

Benefits

- Reduce number of paper error corrections
- Can view & correct/verify in FormsNet3
- Provide documentation in real time instead of years later
- Reduce number of queries for studies, TSCA, CVDR, etc.
- Current time data checking
# Query Management

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## Recipient Information

## Forms

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**CIBMTR**  
**CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH**
Query Management

Specify the planned cell source(s) for this HCT:

2. Autologous

- yes
- no
Query Management

Query Comments

Question #2 - Autologous (Instance #1)

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<Other>

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Query Management

Specify the planned cell source(s) for this HCT:

[2 Autologous]

- yes
- no
**Query Management**

### Recipient Forms

#### Search by Type:
- **CRID**

#### Search For:
- 0002874107

#### Forms

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Where to Send Forms & Corrections?

Email

CIBMTRRecipientForms@nmdp.org

Fax

763-406-8719
(formerly 612-884-8719)
Consolidation therapy

Question 1 – Consolidation Therapy:
Pre-TED Form 2400 question 456 asks how many cycles of induction therapy were required to achieve CR. How do you answer when the patient had one induction cycle that was considered an induction failure but then the patient achieved remission on consolidation therapy?

Answer:
In a case like above, report that it took two cycles of induction therapy to achieve a CR. The second phase of chemotherapy is known as consolidation therapy. Induction therapy is termed as the first or primary line of treatment with the goal of reducing the number of cancer cells and making the cancer vulnerable to additional treatment. Induction therapy can include a wide variety of treatment methods and the application and dosage are determined by weighing the factors involved in the patient’s case. Consolidation therapy is used when an ALL (or AML) patient has achieved a hematologic remission in response to induction therapy. The goal of consolidation therapy is to destroy any remaining leukemia cells and sustain remission. If a center chooses to use “consolidation” type therapy as its first therapy to achieve a CR, the “consolidation” therapy should be reported as induction therapy. If the patient achieved a CR after the 2nd line of therapy, the disease status should be reported as CR, not as a PIF.
Centers for Medicare and Medicaid (CMS) to expand the disease indications for which Medicare beneficiaries have coverage for HCT

- Approved coverage for HCT for sickle cell disease, multiple myeloma and myelofibrosis within the context of Coverage with Evidence Development (CED).

- Next steps:
  - NMDP will work with CIBMTR and the physician community to design the necessary clinical studies
    • Similar to the MDS study
  - Seek approval of the study from CMS so enrollment of qualifying patients can begin
  - Process will take several months.
Discussion Topic

Should the recipient transfer process be made electronic in FormsNet3?
Questions