Form Revision

Stephanie Meyers

Tuesday, February 2, 2021 12:50 – 1:35

There are no conflicts of interest to disclose.

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Objectives

Form Revision Process

2020 Recap

2021 What's Coming

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Form Revision Process

Forms Revision Process

Six Steps

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Step 1: Plan

Selection and Planning

- Select forms to be revised and create quarterly release roadmap
  - Draft proposed schedule of forms up for revisions
  - 4 quarterly releases each year
    - Winter (January)
    - Spring (April)
    - Summer (July)
    - Fall (October)
  - Annual planning tool, subject to change

Step 2: Prepare

Preparation

- Meet with assigned scientific director to compile recommendations
- Communicate upcoming revisions
- Gather feedback from both internal and external stakeholders
- **Participation!**
  - Provide feedback
  - Volunteer to participate in Initial Review Committee (IRC) meetings

***High volume reporting centers individually contacted*

Preparation

- Prepare draft revision and materials for the IRC based on the following:
  - Comments / suggestions received
  - Tickets submitted to CIBMTR Center Support
  - Validation errors that have been overridden
  - Override comments and queries
  - Audit changes made to the forms
  - “Unknown” usage
  - Review “other, specify” fields

Step 3: Revise

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Initial Review Committee (IRC) Meeting(s)

- Meeting(s) to review, discuss, and revise applicable forms
- **This is the best opportunity to be actively involved in discussion!**
- Includes:
  - Field expert physicians, data managers, and CIBMTR staff (Audit, AGNIS, Data Quality, Metadata, FormsNet3 SMEs, etc.)
- Q&A Meeting allows for form piloting
- Instruction Manual and change summaries drafted

Step 4: Review

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Internal Impact Assessments

Standard Impact Assessment

- Review form changes
- Identify problem areas

Validation Impact Assessment

- Develop all form validations
- Reduce data errors

Step 5: Approve

Approval

- Discuss forms changes at weekly leadership meeting
- Obtain final approval from Scientific Directors
- Conduct burden testing
  - Request centers to volunteer for time studies
  - Draft Manuals sent to data managers to request feedback

Burden Testing

- Contact 10-20 sites to request time study completion
  - Complete forms for 2-5 recipients and fill out burden testing tracker

- **Why Should You Participate?**

✓ Allows CIBMTR to estimate burden and determine appropriate reimbursement

✓ Assists centers with resource allocation

✓ Opportunity to provide feedback on draft manuals

✓ Results anticipated to be posted to the Portal for reference

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Burden Testing Tracker

CIBMTR Form Time Study [form ID]

CCN #:

Form:	CRID #	HCT Type	Time to Gather Data (minutes)	Time to Complete Form (minutes)	% Electronic Source Data	% Hard Copy Source Data	Person Completing Form	Comments

Person Completing Form	Time in Position (0-6mo, 6mo-1yr, 1-2yrs, 3+ yrs)	Is Data Reporting Your Primary Responsibility?

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

OMB Clearance Process

- **Required for TED level data**
  - -Pre-TED 2400
  - -Disease Classification 2402
  - -Infectious Disease Markers 2004
  - -HLA 2005
  - -Infusion 2006
  - -Post-TED 2450

- **Long Process**
  - – Expedited (1-3 months for approval)
  - – Standard (7-13 months for approval)

Post- Approval

- Build forms in database
- Compose smart navigation, validation, and Event & Action rules
- Mappings
- Review Form Pairings
- Instruction Manual
- Change Summary
- eLearning

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Step 6: Release

Release

Announcement prior to release

Available for Preview:

- Forms
- Change Summary
- Forms Instruction Manual (as finalized)

Announcement on day of release

In Production:

- Forms
- Change Summary
- Forms Instruction Manual
- eLearnings

Why Are Form Revisions Important?

Collect relevant, useful, and accurate date

-

Harmonization with other registries

Research study needs

2020 Recap

2020 Quarterly Releases

Winter (January) 2020

Spring (April) 2020

Documents to Review

- TCT 2020 Conference Materials
- Archived Release Highlights
- COVID-19 Updates
  - COVID-19 Data Collection FAQ

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Summer (July) 2020 Release

Forms
Sickle Cell Disease (SCD) (2030 / 2130)
Mylotarg Supplemental (2543)

Combined Follow-Up (hard stop) Updates **Submission timeline starts over when a new HCT or genetically modified cellular therapy requiring ongoing follow-up is reported**
Post-HCT (2100)
Post-CT (4100)

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

SCD Revision Highlights

Updated into sections

1. Diagnosis
2. Physical Assessments
   - Post HCT only: Abdominal girth and BP
3. Transfusion Therapy
   - Pre-HCT only: Regular vs. Chronic with start and stop dates
4. Iron Therapy
   - Pre-HCT Only
5. Hepatic Assessments
   - Liver MRI added
6. Pulmonary Assessments
   - 6 minute walk test
7. Renal Assessments
   - Urine albumin and serum creatinine
8. Cardiovascular assessments
   - More echo assessments
   - Removed EKG
9. Splenic Assessments
10. Priapism
11. Acute Chest Syndrome
12. Pain
13. Avascular Necrosis
14. Other Symptoms
15. CNS Vasculopathy
    - Made into “instances” for each event type
16. Other modifying therapies
    - Post-HCT only: Hb electrophoresis questions
17. Reason for Transplant /Disease Status

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Revision Highlights

Mylotarg Supplemental (2543)	Captures supplemental data on Mylotarg treatment received pre-infusion
Combined Follow-up (hard stop) Updates	Defined hard stop and custom enabling / disabling • Reduces duplication, redundancies, and data submission burden when infusions for both HCT and genetically modified CT have been received

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Fall (October) 2020 Release

Forms
Aplastic Anemia (2028 / 2128)
Pre-TED: Disease Classification (2402)
Lymphoma Pre-Infusion (2018)
Recipient Baseline (2000)
Post-HCT Follow-up (2100)

APL Pre-Infusion F2028 Revision Highlights

- Forms last revised in 2007 
  - Numerous additions
    - Bone marrow cellularity and blasts
    - Inherited bone marrow failure screening
    - Family history
  - Cytogenetics and genetic mutational panel, etc.
  - Laboratory Studies updated to “check all that apply” and includes additional options
  - Removed questions to capture sensitivity to cross-linking agents

APL Post-Infusion F2128 Revision Highlights

- Removed reticulocyte level (uncorrected)
- Added questions to capture:
  - Graft failure
  - Autologous recovery
  - Bone marrow examination & cytogenetic results

Revision Highlights

Lymphoma Pre-Infusion (2018)	Added option for “Waldenstrom macroglobulinemia / Lymphoplasmacytic lymphoma” as it was missing
Recipient Baseline (2000)	Added options for “Not done” and “Not applicable (all viral testing negative)” to Q38 and “Not done” to Q100
Post-HCT Follow-up (2100)	Removed field for “NMDP Donor ID” as the new field for “Global Registration Identifier for Donors (GRID)” should now be utilized.

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Winter (January) 2021 Release

Forms
Request for Recipient Transfer (2801)
Pre-TED (2400)
Pre-Cellular Therapy Essential Data (4000)
Cellular Therapy Essential Data Follow-up (4100)
Cellular Therapy Product (4003)
Cellular Therapy Infusion (4006)
Pregnancy (3501)

“Consent Tool”

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Revision Highlights

- Cellular Therapy Package Change Summary:
  - Reference **Cell Therapy** Presentation
- Consent Tool Overview
  - Reference **Consent and You – What it All Means** Presentation
- Major Takeaway
  - CIBMTR research database consent REMOVED from CTED (4000) and Pre-TED (2400), as consent will be captured via the Consent Tool
    - Supports capturing consent and recipient contact information pre-infusion earlier in the data collection process

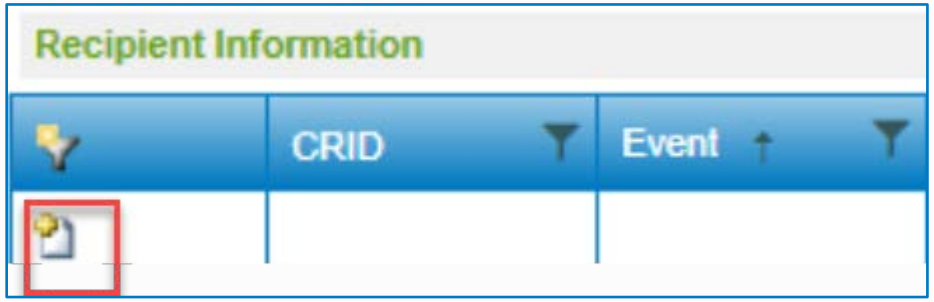
Transfer F2801 Revision Highlights

- Now a fillable, interactive PDF document!

- Added questions to reduce CRC follow-up within CIBMTR Center Support
  - "Agreed upon effective date (date the transferring TO center assumes responsibility for the recipient)"
  - "Did the transferring TO center create a duplicate CRID?"
  - "Reason for transfer"

Pregnancy F3501 Process Updates

- Intent to collect a **single** F3501 for each pregnancy event
- Complete form as soon as it is known when a recipient or recipient's partner is pregnant
  - The form can also be created on-demand as applicable



- <u>Return to the form to ensure outcome of pregnancy is captured</u>

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

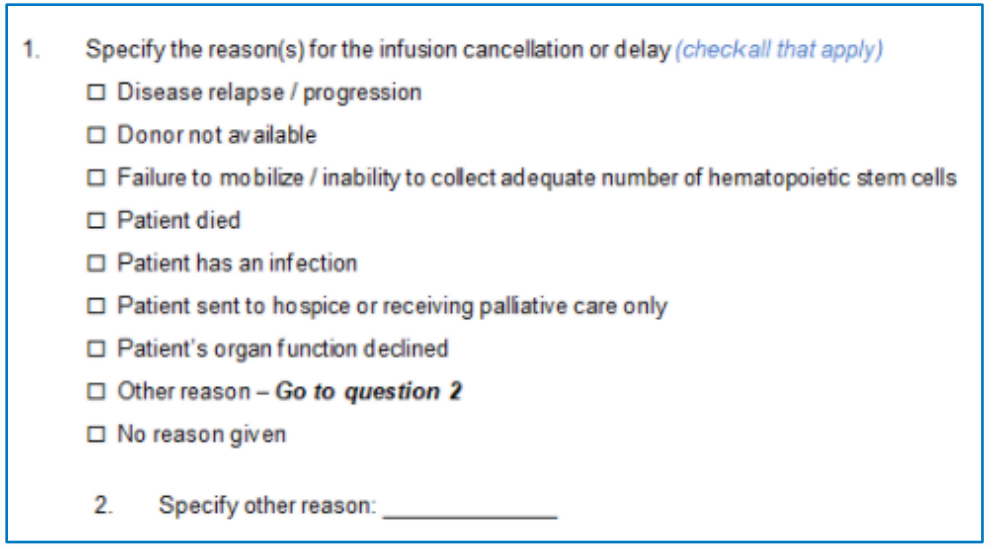
2021 What's Coming

Spring (April) 2021 Release

Forms
Infusion Canceled or Delayed (2008)
Post-TED (2450)
Plasma Cell Disorders (2016 / 2116)
Recipient Death Data (2900)

Infusion Canceled or Delayed F2008 Revision Highlights

- Now only TWO questions!
  - Removed irrelevant questions
  - Added options “failure to mobilize / inability to collect adequate number of hematopoietic stem cells” and “no reason given”
- Electronic, on-demand form in FN3



1. Specify the reason(s) for the infusion cancellation or delay *(check all that apply)*
   - ☐ Disease relapse / progression
   - ☐ Donor not available
   - ☐ Failure to mobilize / inability to collect adequate number of hematopoietic stem cells
   - ☐ Patient died
   - ☐ Patient has an infection
   - ☐ Patient sent to hospice or receiving palliative care only
   - ☐ Patient’s organ function declined
   - ☐ Other reason – ***Go to question 2***
   - ☐ No reason given

2. Specify other reason: _____

CIBMTR® CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

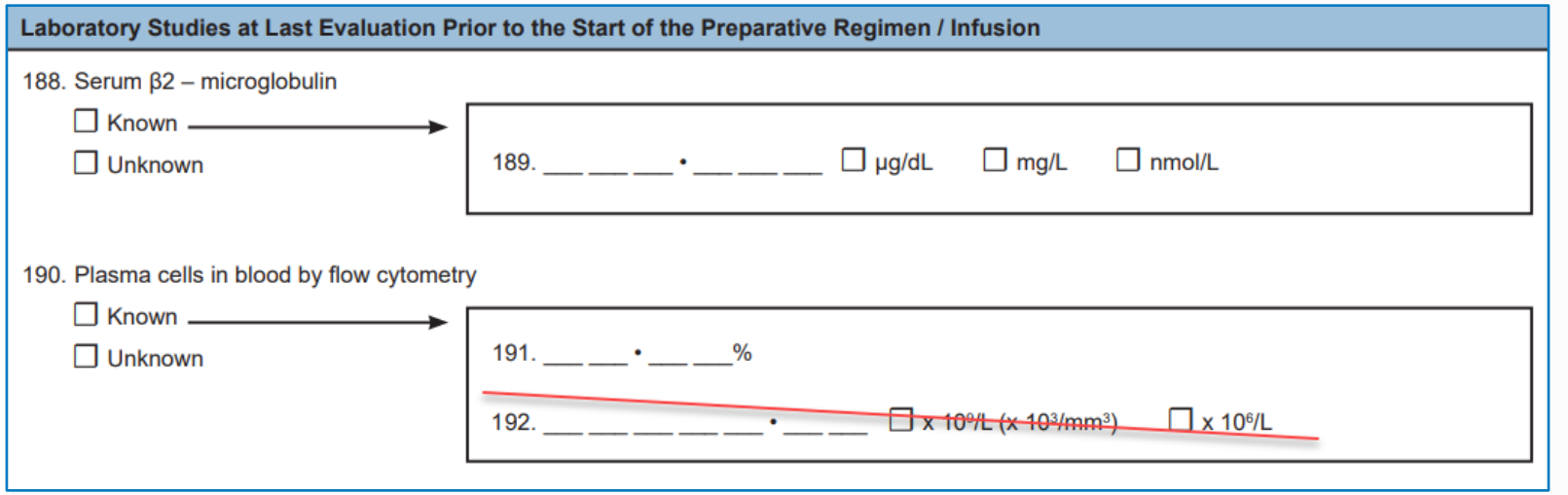
Post-TED F2450 Revision Highlights

- Removed primary and contributing causes of death, as the Recipient Death Data Form (2900) will be completed

The F2900 collects the same information, so we'll use only <u>one</u> form to capture the data!

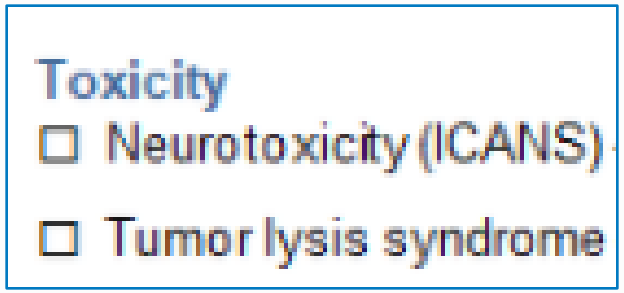
PCD (2016 / 2116) Revision Highlights

- Treatment options for “Belantamab mafodotin (Blenrep)”, “Ciltacabtagene autoleucel”, and “Idecabtagene vicleucel” added to therapy dropdown options
- Question to capture absolute number of plasma cells in blood by flow cytometry removed



Recipient Death Data F2900 Revision Highlights

- Added “Toxicity” sub-section with options “neurotoxicity [ICANS]” & “tumor lysis syndrome”



- Alphabetized sub-sections headers and dropdown options within

Summer (July) 2021 Release

* Revisions “in progress”

Forms
Request for Recipient Transfer (2801)
Post-HCT (2100)
Pre-TED: Disease Classification (2402)
Immune Deficiencies (2031 / 2131)

Participation in IRC Meetings and / or Time Studies

THANK YOU!

- 10029 -Children's Medical Center Dallas
- 10048 -Children's Healthcare of Atlanta at Egleston
- 10050 -University of Illinois Medical Center at Chicago
- 10052 -The Blood and Marrow Transplant Program at Northside Hospital
- 10057 -Penn State Hershey Medical Center
- 10102 -Morgan Stanley Children's Hospital of New York-Presbyterian - Columbia University Medical Center
- 10103 -Children's Hospital & Research Center Oakland
- 10117 -Fred Hutchinson Cancer Research Center
- 10138 -Children's Hospital of Los Angeles
- 10142 -Vanderbilt University Medical Center
- 10143 -City of Hope
- 10150 -Moffitt Cancer Center
- 10151 -M.D. Anderson Cancer Center
- 10159 -Barnes Jewish Hospital
- 10162 -Duke University Medical Center; Pediatric Blood and Marrow Transplant
- 10193 -Cook Children's Medical Center
- 10198 -Roswell Park Cancer Institute
- 10205 -Mount Sinai Medical Center - 2
- 10208 -University of Kansas
- 10211 -Mayo Clinic Rochester
- 10778 -Auckland City Hospital
- 10831 -Massachusetts General Hospital
- 10840 -National Heart Lung and Blood Institute - NIH
- 10989 -AFBMTC
- 11052 -Washington University/St. Louis Children's Hospital

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Roadmap Schedule

- Gene Therapy – Fall (October) 2021
- CT Series & Thalassemia – Winter (January) 2022
- Fanconi Anemia – Spring (April) 2021

Provide Feedback!

- Submit a ticket via CIBMTR Center Support to provide comments / suggestions at any time
- All change requests are documented and reviewed on a case-by-case basis
    - Some changes can occur in a monthly maintenance release
        - Addition of floating text
        - Smart navigation and validation updates
    - Other changes require the form to be revised
        - Addition / removal of questions
        - Updating form layout

How Can I Help?

- What would you like to see change in Form Revision?
- If you could change one thing about the Form Revision Process, what would it be?
- What else would be helpful for you?

Thank You!

Contact CIBMTR Center Support at any time with questions, comments, or feedback. This is strongly encouraged!

Thank you furry much!

Questions?