Form Revision
Stephanie Meyers
Tuesday, February 2, 2021 12:50 – 1:35

There are no conflicts of interest to disclose.
Form Revision Process
Forms Revision Process
Six Steps

Plan
Prepare
Revise
Review
Approve
Release
Step 1: Plan

- Plan
- Prepare
- Revise
- Review
- Approve
- Release
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

1. Plan
2. Prepare
3. Review
4. Approve
5. Release

Next step: Revise
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

- Plan
- Prepare
- Revise
- Approve
- Release
- Review
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

- Plan
- Prepare
- Revise
- Review
- Release
- 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
# Burden Testing Tracker

## CIBMTR Form Time Study [form ID]

<table>
<thead>
<tr>
<th>Form</th>
<th>CRID #</th>
<th>HCT Type</th>
<th>Time to Gather Data (minutes)</th>
<th>Time to Complete Form (minutes)</th>
<th>% Electronic Source Data</th>
<th>% Hard Copy Source Data</th>
<th>Person Completing Form</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Person Completing Form (0-6mo, 6mo-1yr, 1-2yrs, 3+ yrs)</th>
<th>Time in Position</th>
<th>Is Data Reporting Your Primary Responsibility?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

CCN #: 

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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
Step 6: Release

- Plan
- Prepare
- Revise
- Review
- Release

CRP/DM CONFERENCE 2021 | 20
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

Documents to Review

- TCT 2020 Conference Materials
- Archived Release Highlights
- COVID-19 Updates
  - COVID-19 Data Collection FAQ
### Summer (July) 2020 Release

#### Forms

<table>
<thead>
<tr>
<th>Disease/Therapy</th>
<th>Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sickle Cell Disease (SCD)</td>
<td>2030 / 2130</td>
</tr>
<tr>
<td>Mylotarg Supplemental</td>
<td>2543</td>
</tr>
</tbody>
</table>

#### 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.

<table>
<thead>
<tr>
<th>Follow-Up Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-HCT</td>
<td>2100</td>
</tr>
<tr>
<td>Post-CT</td>
<td>4100</td>
</tr>
</tbody>
</table>
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
**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
## Forms

<table>
<thead>
<tr>
<th>Form Description</th>
<th>Form Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aplastic Anemia (2028 / 2128)</td>
<td></td>
</tr>
<tr>
<td>Pre-TED: Disease Classification (2402)</td>
<td></td>
</tr>
<tr>
<td>Lymphoma Pre-Infusion (2018)</td>
<td></td>
</tr>
<tr>
<td>Recipient Baseline (2000)</td>
<td></td>
</tr>
<tr>
<td>Post-HCT Follow-up (2100)</td>
<td></td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Section</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphoma Pre-Infusion (2018)</td>
<td>Added option for “Waldenstrom macroglobulinemia / Lymphoplasmacytic lymphoma” as it was missing</td>
</tr>
<tr>
<td>Recipient Baseline (2000)</td>
<td>Added options for “Not done” and “Not applicable (all viral testing negative)” to Q38 and “Not done” to Q100</td>
</tr>
<tr>
<td>Post-HCT Follow-up (2100)</td>
<td>Removed field for “NMDP Donor ID” as the new field for “Global Registration Identifier for Donors (GRID)” should now be utilized.</td>
</tr>
</tbody>
</table>
## Winter (January) 2021 Release

**Forms**

<table>
<thead>
<tr>
<th>Form Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Request for Recipient Transfer</td>
<td>2801</td>
</tr>
<tr>
<td>Pre-TED</td>
<td>2400</td>
</tr>
<tr>
<td>Pre-Cellular Therapy Essential Data</td>
<td>4000</td>
</tr>
<tr>
<td>Cellular Therapy Essential Data Follow-up</td>
<td>4100</td>
</tr>
<tr>
<td>Cellular Therapy Product</td>
<td>4003</td>
</tr>
<tr>
<td>Cellular Therapy Infusion</td>
<td>4006</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>3501</td>
</tr>
</tbody>
</table>

"Consent Tool"
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

• Return to the form to ensure outcome of pregnancy is **captured**
2021 What’s Coming
## Spring (April) 2021 Release

### Forms

<table>
<thead>
<tr>
<th>Form</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infusion Canceled or Delayed</td>
<td>(2008)</td>
</tr>
<tr>
<td>Post-TED</td>
<td>(2450)</td>
</tr>
<tr>
<td>Plasma Cell Disorders</td>
<td>(2016 / 2116)</td>
</tr>
<tr>
<td>Recipient Death Data</td>
<td>(2900)</td>
</tr>
</tbody>
</table>
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
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 one 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

Toxicity
- Neurotoxicity (ICANS)
- Tumor lysis syndrome
## Summer (July) 2021 Release

* Revisions “in progress”

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<td>Pre-TED: Disease Classification (2402)</td>
</tr>
<tr>
<td>Immune Deficiencies (2031 / 2131)</td>
</tr>
</tbody>
</table>
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
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?