CIBMTR Center Support Updates and Frequently Asked Questions by Centers

Eileen Tuschl, DNP, RN, ACNS-BC
Sr. Manager, Clinical Data Operations and Education
Angela Hauck, BS, SLP
Manager, CIBMTR Center Support

No Disclosures
Objectives

• Review the CIBMTR Center Support survey results
• 2020 in Review
• Recommendations to network centers
• Enhancements
• Education and Training
CIBMTR Center Support Survey: 6 Month (November 2019) and 1 Year (June 2020)
Background

• Transplant centers were surveyed about CIBMTR Center Support at 6-months (November 2019) and 1-year (June 2020) post Go-live

• The 6-month results were presented at the TCT DM/CRP Conference last year (February 2020)
Demographics

1 Year: July 2020
• 180 Transplant Centers Responded for a Center Response Rate: **47.7%**
  – Domestic Centers: 122 (61.3%)
  – International Centers: 58 (32.6%)

• Overall User Response Rate: **61.2%**

6 Months: November 2019
• 180 Transplant Centers Responded for a Center Response Rate: **47.7%**
  – Domestic Centers: 123 (61.8%)
  – International Centers: 57 (32.0%)

• Overall User Response Rate: **85.6%**
Overall CIBMTR Center Support Application Satisfaction

1 Year: July 2020

- **97%** of respondents stated they had a **positive** experience with the CIBMTR Center Support application

6 Months: November 2019

- **86%** of respondents stated they had a **positive** experience with the CIBMTR Center Support application
Staff Knowledge and Interaction

1 Year: July 2020

- **97%** had a **positive experience** with CIBMTR Center Support staff
- **81%** reported CIBMTR Center Support staff **addressed** their questions
  - **92%** further reported they felt CIBMTR Center Staff had the **ability** to **answer** their questions

6 Month: November 2019

- **88%** had a **positive experience** with CIBMTR Center Support **staff**
- **80%** felt their **questions, requests, or issues** had been **addressed** and/or resolved to their satisfaction
Response Time: July 2020

On average, 94% felt CIBMTR Center Support resolved technical (add, delete, reset, duplicate CRID, center maintenance) questions within two business days.

On average, 96% felt CIBMTR Center Support resolved your data reporting questions within seven business days.
Better Support in the Future Themes

**1 Year: July 2020**

**Theme 1: Ticket Responses**
- Allow more time for a center to respond before a ticket is closed
- Consistent responses

**Theme 2: Updates to CIBMTR Center Support Portal**
- Include the CRID in the subject line of the ticket
- Include the CCN # in the ticket request

**Theme 3: Other**
- Training for Data Managers
- Have manual updates congruent with form revisions

**6 Month: November 2019**

**Theme 1: Ticket Responses**
- Not addressing all questions within one ticket
- Regurgitating the manual, copy/paste
- Responses are too vague
- Tickets are closed before site confirms it’s resolved

**Theme 2: Response Times**
- SLA too long (especially 7 Day Clinical SLA)
- Ticket is not answered in a timely manner
- Waiting on responses delays time to complete form

**Theme 3: Removal of assigned CRC**
- I miss our CRC
- I wish I could pick up phone to talk to CRC
- Miss the conversational aspect with an assigned CRC
Key Points

• 97% Overall CIBMTR Center Support Application Satisfaction
• 95% of tickets met response times
• 97% had positive interactions with CIBMTR Center Support Staff
2020
In Review
2020 Enhancements and Training

- **June 2020**: Weekly eBlasts on Tuesdays
- **March 2020**: Tickets automatically sent directly to SME
- **April 2020**: Tickets in the Resolved Complete state cannot be reopened
- **24 Aug. 2020**: CCN# was added to the CIBMTR Center Support Portal
- **28 Aug. 2020**: Pending categories updated; ticket resolves on its own after 7 business days giving center 7 days to reply
- **23 Sep. 2020**: Dashboard Update: CRID, Category, Sub-category, and Keep in the loop
- **September 2020**: New data manager virtual onboarding
- **November 2020**: Attachment Notification Email Updated – Must access via Dashboard
- **November 2020**: Cell Therapy Data Manager Forum
2020 Ticket Breakdown

- Total Submitted Tickets: 17,792
- Daily Ticket Average: 68.4
Types of Tickets Submitted in 2020

- Data Reporting Questions: 30%
- Technical: 27%
- Cell Therapy: 13%
- Clinical Data Validation: 3%
- COVID Impact to HCT: 3%
- Clinical Data Quality: 4%
- CIBMTR Center Maintenance: 7%
- CPI/CTA: 4%
- COVID Impact to HCT: 3%
- Other: 9%

Other: 9%
Recommendations to Network Centers
Reset a Form

• Any form that is in the SVD (save) status can be reset
• Simply open the form in ‘Edit’ mode

Scheduled form

Unscheduled form

Clear Form
• Clears all data entered on the form and resets the form status back to DUE
• The Clear Form icon only appears in the Form Action Menu for scheduled forms.
• Once the user clicks the Submit icon, the Clear Form icon will no longer be an option in the Form Action Menu.
• If you need to have your form cleared or reset after it has been submitted, submit a ticket to CIBMTR center support.

Cancel Form
• Clears all data entered on the form and deletes the form completely from the system
• The Cancel Form icon will only appear in the Form Action Menu for unscheduled forms.
• Once you click the Submit icon, the Cancel Form icon will no longer be an option in the Form Action Menu.
• If you need to have your form deleted after it has been submitted, submit a ticket to CIBMTR center support.
Recommendations

• When submitting a ticket to CIBMTR Center Support for multiple myeloma, you MUST also attach a completed disease tracker
  – The tracker can be found in the forms instruction manual in Appendix G
Recommendations

• Clinical Questions
  – Our CIBMTR Support staff are not providers and/or nurses, therefore, cannot answer clinical questions
  – Please bring clinical questions to your center providers first, if possible

• For example: disease classification/status questions should be run by physicians/providers first
  – then submit a ticket if there are questions about how to report to the disease classification or disease status in FN3
Category, Sub-Categories, & Response Times

*What is your question regarding?

**Short Description**

I.E. Topic - TREAT THIS SECTION LIKE THE SUBJECT LINE OF AN EMAIL - NO PHI/PII in this section

**Describe your question in detail**

Enter question HERE, NOT in the Short Description - CAN contain PHI/PII
Upcoming Enhancements
<table>
<thead>
<tr>
<th>Category</th>
<th>Sub-Category</th>
<th>Response Time (Max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access</td>
<td>Portal, FN3, Okta Verify</td>
<td>5 Business Days</td>
</tr>
<tr>
<td>CIBMTR Center Maintenance</td>
<td>Center Staff (Update, Departing, New), Change Reporting Track, Entitlement Survey</td>
<td>5 Business Days</td>
</tr>
<tr>
<td>CIBMTR Corporate Studies, Registries, and Trials</td>
<td>Select Study from drop-down</td>
<td>5 Business Days</td>
</tr>
<tr>
<td>COVID Impact to HCT</td>
<td>COVID Impact on HCT Question Spreadsheet Submission</td>
<td>7 Business Days</td>
</tr>
<tr>
<td>CPI</td>
<td>Forms Due List</td>
<td>2 Business Days</td>
</tr>
<tr>
<td>CTA</td>
<td>CTA Process Question, CTA HCT List Submission</td>
<td>5 Business Days</td>
</tr>
<tr>
<td>CVDR</td>
<td>CVDR Question, CVDR Submission Process</td>
<td>5 Business Days</td>
</tr>
<tr>
<td>Data Transformation (Beta Sites Only)</td>
<td>Contextual Data Request-Test Data, Contextual Data Request-Production Data</td>
<td>7 Business Days</td>
</tr>
<tr>
<td>DBtC</td>
<td>Data Inquiry, Missing Data, Exporting CIBMTR Portal Data</td>
<td>5 Business Days</td>
</tr>
<tr>
<td>Category</td>
<td>Sub-Category</td>
<td>Response Time (Max)</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>---------------------------------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Form Revision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FormsNet3</td>
<td>Queries/ ECF</td>
<td>2 Business Days</td>
</tr>
<tr>
<td></td>
<td>Survivorship Discrepancies</td>
<td>5 Business Days</td>
</tr>
<tr>
<td></td>
<td>Reset a Form</td>
<td>2 Business Days</td>
</tr>
<tr>
<td></td>
<td>Add a Form</td>
<td>2 Business Days</td>
</tr>
<tr>
<td></td>
<td>Delete a Form</td>
<td>2 Business Days</td>
</tr>
<tr>
<td></td>
<td>Errors and/or Validation</td>
<td>5 Business Days</td>
</tr>
<tr>
<td>FormsNet3 Reporting Question</td>
<td>NONE</td>
<td>5 Business Days</td>
</tr>
<tr>
<td>HLA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory Virus Post-Infusion Data Form (2149)</td>
<td>Question about completing Form 2149 Reinfection</td>
<td>5 Business Days</td>
</tr>
<tr>
<td>TCSA</td>
<td>COVID data from AGNIS centers</td>
<td>Ongoing</td>
</tr>
<tr>
<td></td>
<td>TCSA Submission</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Submit EC for AUDITED form</td>
<td></td>
</tr>
<tr>
<td>Training</td>
<td>eLeanings</td>
<td>5 Business Days</td>
</tr>
<tr>
<td></td>
<td>New Manager Onboarding</td>
<td></td>
</tr>
<tr>
<td>Transfer Form</td>
<td>Transfer Contact Information</td>
<td>7 Business Days</td>
</tr>
<tr>
<td></td>
<td>Transfer Form</td>
<td></td>
</tr>
</tbody>
</table>
Education and Training
Education and Training

- NEW DATA MANAGER ONBOARDING
- SELF-GUIDED ONBOARDING
- EDUCATIONAL WEBINARS FOR ONGOING LEARNING
- ELEARNING'S
Live Interactive New Manager Onboarding

- CIBMTR Data Operations offers new data manager onboarding twice a year:
  - **In-person** each **February** at The TCT | Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR and
  - each **September virtually**
- New Data Manager Onboarding is for **individuals with 6 months or less experience** at their center.
- The classes include **interactive training** in our FormsNet3 training environment along with topics that are pertinent to new data managers to submit quality data.
Onboarding and Webinars

Self-Guided Data Manager Onboarding

- Will include:
  - week-by-week schedule, job aids, worksheets, and a competency checklist

New Center Onboarding

- Will include:
  - facts and figures, new center FAQ, roadmap to becoming a CIBMTR center, IRB onboarding, and data management onboarding
eLearnings

Online Training
Network learners will access updated and new eLearnings via the CIBMTR Portal. During the transition, eLearnings will be housed on two platforms until the full transition to the Portal is complete. Both platforms are outlined [HERE].

Educational opportunities are continually being developed as part of our commitment to improve data quality and provide data managers with resources for data reporting. eLearnings allow us to cater to various styles of learning by...

[Welcome to CIBMTR Portal]

[Data Management]

[Training & eLearning]

[Link to knowledge check]
Frequently Asked Questions in CIBMTR Center Support
HCT Data Reporting Questions

- Disease Status
- Disease Classification
- HCT Product and Infusion
- Co-Morbidities
- Lines of Therapy
- Method of Disease Assessment
Disease Classifications

• If the recipient has **both NHL and HL** – it is important to determine which disease is **active** prior to the start of the preparative regimen to determine what should be reported
  – Consult the physician to make this determination

• If a recipient is being transplanted for both **active NHL** and **active HL** that were both diagnosed at different timepoints.
  – Report this as NHL using the “Other B-cell Lymphoma” (specify on the Form 2402)
  – Complete the Disease Classification questions for NHL
Transformations

- **Form 2402**: If the recipient has multiple types of lymphoma at diagnosis or has a transformation
  - Report the **second** lymphoma diagnosis date (histology for which the recipient is receiving a transplant or cellular therapy) for the primary **diagnosis** (Q1 and Q380)
  - Report the **first** lymphoma diagnosis date as a **transformation** (Q385-388)

- **Form 2018**: If the recipient has multiple types of lymphoma at diagnosis or has a transformation
  - Report the **least aggressive** lymphoma histology at **diagnosis** (Q1)
  - report the **most aggressive** lymphoma as a **transformation** (Q83-85).

- For forms 2018 and 2402 there is a cross form validation in regards to lymphoma transformation/diagnosis
Best Response to HCT - CCR

A recipient in complete metabolic and radiographic remission at the time of infusion has a disease relapse detected on their first PET/CT scan post-HCT

100 Day Follow-Up Form

• **Question 1**: Report “Continued complete remission.”
  – This option should be used for all recipients in radiographic CR at the time of infusion regardless of post-infusion disease assessments.

• **Question 4**: Report “Continued complete remission.”
  – This option should be used for all recipients in metabolic CR at the time of infusion regardless of post-infusion disease assessments.
Best Response to HCT

A recipient is in **complete radiographic** remission and **partial metabolic** remission **at the time of infusion**. They achieve a **complete metabolic remission** during the **100-day reporting** period and are **not evaluated by CT** (radiographic) in this reporting period. The following should be reported as the best response to HCT by both PET and CT.

**Form 2118**

- **Question 1**: Report “**Continued complete remission.**”
  - This option should be used for all recipients in radiographic CR at the time of infusion regardless of post-infusion disease assessments.

- **Question 4**: Report “**Complete remission.**”
  - This option should be used for all recipients in metabolic CR at the time of infusion regardless of post-infusion disease assessments.
Best Response to HCT - Relapse

A recipient in partial metabolic and radiographic remission at the time of infusion achieves a complete metabolic and radiographic remission during the 100-day reporting period (on 5/1/2014).

100 Day Follow-Up Form:

• **Question 1**: Report “Complete Remission.”
  – Use this option to indicate a radiographic CR was achieved post-infusion for recipients not in radiographic CR at the time of infusion.

• **Question 4**: Report “Complete Remission.”
  – Use this option to indicate a metabolic CR was achieved post-infusion for recipients not in metabolic CR at the time of infusion.
Then a **PET** scan performed during the **6-month reporting period** detects **relapse** and the recipient’s disease status remains “Relapse” on the 6-month date of contact despite multiple treatments

**Six Month Follow-Up Form:**

- **Question 1:** Report **“Complete Remission.”**
  - Use this option to indicate a **radiographic** CR was achieved post-infusion for recipients not in metabolic CR at the time of infusion.

- **Question 2:** Report **“Yes.”**
  - The date of best response was reported on the day 100 follow-up form.

- **Question 4:** Report **“Complete Remission.”**
  - Use this option to indicate a **metabolic** CR was achieved post-infusion for recipients not in metabolic CR at the time of infusion.

- **Question 5:** Report **“Yes.”**
  - The date of best response was reported on the day 100 follow-up form.
Disease Status

• Current disease status by (PET) metabolic criteria should be reported in Q89 (Form 2118)
  – Only report not assessed
    • If the primary disease is a non-PET avid lymphoma
    • A PET scan was not performed since infusion and no way to determine disease status

• Once a particular disease status is achieved, that same disease status can be reported until there is evidence of relapse/progression
  – Once the recipient achieves CR, continue to report CR even if a PET/CT was not performed in the reporting period
  – If no disease specific assessments occurred within the reporting period, report the date of any disease related assessment (clinical assessment, labs…etc.) as the date assessed
Lines of Therapy

• If this is a subsequent infusion and the 2018 was completed for the previous infusion
  – Lines of therapy **do not** need to be reported in duplication on the additional 2018
  – Report from post previous infusion to time of preparative regimen (or infusion) for the current HCT or cellular therapy
  – If no 2018 was completed previously, all lines of therapy from original diagnosis to current preparative regimen (or infusion) will have to be completed

• Do **not** include preparative regimen from the prior HCT as a LOT

• If the recipient’s lymphoma histology transformed between diagnosis and the start of the preparative regimen, all therapy administered from diagnosis (of the original lymphoma) until the start of the preparative regimen should be reported
Transformation Pre-HCT

- A patient diagnosed with MPN transforms to AML prior to HCT. The patient is still showing evidence of MPN relapse but meets AML CR criteria at the last evaluation prior to HCT. Can the patient be relapsed for MPN but CR for AML?
Reporting Pre-HCT Disease Status on the 2402

AML status

**Status at transplantation / infusion**

91. What was the disease status? (based on hematological test results)

- Primary induction failure - **Go to question 95**
- 1st complete remission (no previous bone marrow or extramedullary relapse) (include CRI) - **Go to question 92**
- 2nd complete remission - **Go to question 92**
- ≥ 3rd complete remission - **Go to question 92**

MPN status

**Status at transplantation / infusion**

364. What was the disease status?

- Complete clinical remission (CR) - **Go to question 368**
- Partial clinical remission (PR) - **Go to question 368**
- Clinical Improvement (CI)
- Stable disease (SD) - **Go to question 368**
- Progressive disease - **Go to question 368**
- Relapse - **Go to question 368**
- Not assessed
Transformation Post-HCT

- A recipient with Myelofibrosis received an Allo HCT. Disease status prior to transplant was stable disease (SD). On Day +147, the recipient developed a soft tissue mass that was positive for myeloid sarcoma. There was no morphological evidence of increased blasts in the bone marrow or peripheral blood. Can I classify this as progression to AML?
Reporting Post-HCT Disease Status on the 2157

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>276. What is the current disease status?</td>
<td>Complete clinical remission (CR) - Go to question 280, Partial clinical remission (PR) - Go to question 280, Clinical Improvement (CI) - Go to question 277, Stable disease (SD) - Go to question 280, Progressive disease - Go to question 280, Relapse - Go to question 280, Progression to AML - Go to question 280, Not assessed - Go to question 281</td>
</tr>
<tr>
<td>277. Was an anemia response achieved?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>278. Was a spleen response achieved?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>279. Was a symptom response achieved?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>280. Date assessed:</td>
<td>YYYY / MM / DD</td>
</tr>
</tbody>
</table>

Report the date of the assessment that detected the new myeloid sarcoma.
Co-Morbidities

• Psychiatric disorders
  – Presence of any mood, anxiety, or other psychiatric disorder requiring *continuous treatment* during the period of *4 weeks prior to transplant* meet the criteria of a psychiatric disorder
  – Patients who are receiving only “as-needed” medications should **NOT** be reported as having a psychiatric disorder
Thank You and Questions