CIBMTR IT Update

CRP/DM Meeting
February 21, 2018

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Objectives

• Share user experience survey results

• Update on recent accomplishments and future plans

• Ongoing feedback opportunities
Agenda

• Review User Perspective feedback
  • User Perspective Survey in January 2018

• Application releases within the past year
  – FormsNet releases
  – AGNIS updates
  – Data Sharing updates

• 2018 Plans

• Ongoing Feedback opportunities
User Perspective Feedback
January 2018 survey results

• Survey of all FN3 users
• Asked to rank overall satisfaction with FN3 recipient module from 1-10
• 18% of responders gave an overall score of <5
• 70.2% of responders gave an overall score of 5-8
• 11.8% of responders gave an overall score of >8
January survey results (cont.)

• Thank you for taking the time to provide comments and complete the survey
  – We received a large number of responses, including many wonderful suggestions

• Subject Matter Experts will be providing enhanced instructions for less well-known FN3 features
  – Provide updates in the data managers newsletters or e-blasts

• Further review and analysis of responses for features that are not meeting expectations, as well as enhancement suggestions
  – FN3 team is currently working on Enabling/disabling issue, and Application performance
FormsNet – CIBMTR’s electronic data collection system – 2017 Highlights

• FormsNet3 platform enhancements
  – Check all that apply functionality implemented, which allows you to utilize checkboxes to check all applicable answers instead of having to answer yes/no for each option.
    • Will be applied to forms as they undergo revision process
  – Continuing to update tools to improve efficiencies

• Forms Revision
  – To keep forms current with existing clinical practice, released Recipient form updates including 5 pre/post disease insert revisions, 9 new study forms, 1 new form and 5 other revisions
  – Implemented forms to support a Cellular Therapies Registry, including 6 form revisions and 2 new forms.
### TED/CRF & Disease Specific Forms Released 2017 thru Jan 2018

<table>
<thead>
<tr>
<th>TED/CRF Forms</th>
<th>Disease Specific Forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>2400 - Pre-TED (revised as part of split of 2400 into 2400 &amp; 2402)</td>
<td>2010/2110 - Acute Myelogenous Leukemia</td>
</tr>
<tr>
<td>2402- Disease classification (new form)</td>
<td>2011/2111 - Acute Lymphoblastic Leukemia</td>
</tr>
<tr>
<td>2005 - Confirmation of HLA Typing</td>
<td>2012/2112 - Chronic Myeloid Leukemia (CML)</td>
</tr>
<tr>
<td>2100 – Post HCT Follow-up</td>
<td>2018/2118 - Hodgkin and Non-Hodgkin Lymphoma</td>
</tr>
<tr>
<td>2450 – Post TED</td>
<td>2046/2146 - Fungal Infection</td>
</tr>
<tr>
<td>2900 – Death form</td>
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</tbody>
</table>
Study & Cellular Therapy Forms
Released 2017 thru Jan 2018

<table>
<thead>
<tr>
<th>Study forms (new)</th>
<th>Cellular Therapy Forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>2500: Recipient Eligibility Form</td>
<td>4000 - Cellular Therapy Essential Data Pre-Infusion</td>
</tr>
<tr>
<td>2516: MM 17-01 Supplemental Data</td>
<td>4006 - Cellular Therapy Infusion</td>
</tr>
<tr>
<td>2554: CMS Registration Form, 2555: CMS-MF Myelofibrosis Eligibility Form</td>
<td>4100 - Cellular Therapy Essential Data Follow-Up</td>
</tr>
<tr>
<td>2556/2557 Myelofibrosis CMS Study</td>
<td>3500  Subsequent Neoplasms (New)</td>
</tr>
<tr>
<td>2558: CMS-SCD Sickle Cell Disease Eligibility Form</td>
<td>4003 Cellular Therapy Product (New)</td>
</tr>
<tr>
<td>2564: Sanofi Eligibility; 2565: Sanofi Mozobil Supplemental Data Collection</td>
<td></td>
</tr>
</tbody>
</table>
2018 Enhancements

• Updates to FormsNet3 Recipient
  • Ongoing forms revisions quarterly
  • Survival Tool
  • Transfer Form Process (Initial Stage)

• Analyze user experience survey feedback & apply enhancements accordingly.
AGNIS Overview

- AGNIS is a tool that helps centers or vendors facilitate electronic database to database submissions to CIBMTR.

- It’s another way to submit, edit or retrieve CIBMTR form data.

- Allows centers to avoid entering data more than once, i.e. into a local system and again into FormsNet.

- AGNIS submissions use the same validations and rules as FormsNet.
AGNIS Supported Forms

- Transplant centers are able to electronically submit and retrieve 16 CIBMTR recipient outcomes forms
- These forms represent 85% of recipient data collected through FormsNet or AGNIS.
- This includes
  - Seven TED level forms (pre- and post-TED, HLA, IDM, Infusion, Chimerism, and Selected Post-TED)
  - Unique ID Assignment and Indication
  - Five Comprehensive Forms (Baseline, 100 Day Follow-Up, 6 mo. to 2 yr. Follow-up, Annual Follow-Up, and Death)
  - Two disease-specific inserts (Pre- and Post-HCT Hodgkin and Non-Hodgkin Lymphoma)
AGNIS – 2017 Accomplishments

• AGNIS Activity
  – Continued growth in vendors and centers developing tools with AGNIS capabilities
    • 21 centers using AGNIS to submit to CIBMTR and 27 retrieving their FormsNet3 data
  – Released new revisions of 7 AGNIS supported forms

• EBMT-CIBMTR
  – Continuing submission of data from EBMT to CIBMTR for centers with data sharing agreements
  – If you have any questions about this process, please contact your CIBMTR CRC

• Any interest in learning more about AGNIS, just email the team at AGNISsupport@nmdp.org
AGNIS Opportunities/ Challenges

1. Supporting current users and **easing adoption** of the new form revisions

2. **Growing** the number of centers able to utilize and benefit from AGNIS

3. Continuing to look to the **future** and evolve to maintain industry best practices
Data Sharing
Information Resources:
CIBMTR Public Website

Research Tools

The CIBMTR has created several tools and calculators, which are available to CIBMTR community users. These tools were created utilizing data in the CIBMTR Research Database, which includes information on more than 475,000 transplant recipients.

The Disease Risk Index (DRI) tool can be viewed on the CIBMTR website. All other tools can be viewed on the CIBMTR Portal, a specialized and secure, password-protected area for CIBMTR community users.

As an authorized user, you may view, analyze, or download information for your center by accessing different applications on the Portal:

- **CVDR (Center Volumes Data Report):** View details regarding your center’s transplant volume in prior years.
- **Survival Calculator:** Create a one-year predicted survival for allogeneic
The Disease Risk Index (DRI) is a validated tool to categorize groups of patients undergoing allogeneic stem cell transplantation (HCT) for **hematologic malignancy** by disease risk. It is intended for research purposes, to stratify patients in broad disease risk categories for retrospective or prospective studies.

The DRI considers only disease-related parameters (i.e., disease, stage and, for some diseases, cytogenetics) and was developed only for the primary outcome of **overall survival** after HCT.

**Publication Details**

**DRI Assignment Tool**

<table>
<thead>
<tr>
<th>Disease*:</th>
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</thead>
<tbody>
<tr>
<td>Disease Stage*:</td>
<td></td>
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<tr>
<td>DRI Group:</td>
<td></td>
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</table>
VOD Calculator

- New in 2018
- Calculates a risk score to identify patients at high risk for developing veno-occlusive disease within 100 days of allogeneic transplant
- Uses a statistical model developed in conjunction with research done for a Journal of Clinical Oncology publication
- Available on CIBMTR website under the reference center
Welcome to the CIBMTR Portal

The CIBMTR Portal is a specialized and secure, password-protected area for CIBMTR community users. As an authorized user, you may view, analyze, or download information for your center by accessing different applications:

- **CVDR (Center Volumes Data Report)** – View details regarding your center’s transplant volume in prior years.
- **Survival Calculator** – Create a one-year predicted survival for allogeneic transplants based on the three year transplant center specific survival dataset.
  - This application is only available to Medical Directors, Physicians, and Center Administrators.
- **DBtc (Data Back to Centers)** – Access TED-level data your center submitted through FormsNet.
- **eDBtc (enhanced Data Back to Centers)** – Analyze, filter, or download select center CRF- and TED-level data from 2008 to present.
- **CPA (Center Performance Analytics)** – Comparatively analyze your transplant center specific survival data relative to aggregated data from other US centers.
- **Audit Data** – Historical records of CIBMTR audit reports and accompanying documents.

To access the Portal and its applications, you must have a Google account registered with the CIBMTR.

- If you do not have a Google account, you can get one through Google.
- If you have a Google account but have not yet registered with the CIBMTR, please email your Google email address to the CIBMTR Portal Help Desk.
- If you have forgotten your Google password, you can get help from Google.
Survival Calculator – 1 year

- Calculates probability of 1 year survival after allogeneic transplantation for individual patients
- Uses model developed for annual center-specific outcomes analysis for US transplant centers

**Patient One Year Survival Probability Calculator**

**RECIPIENT CHARACTERISTICS**
- Recipient Age:
- Recipient Gender:
- Recipient Race/Ethnicity:
- Recipient CMV Status:
- Karnofsky/Lansky Score at Transplant:
- HCT-CI Comorbidity Score:

**DISEASE CHARACTERISTICS**
- Disease:

**TRANSPLANT CHARACTERISTICS**
- Prior Autologous Transplant:
- Graft Type:

**DONOR CHARACTERISTICS**

*All fields are required!

Predicted Patient One Year Survival Probability Estimate: 0.00

95% confidence interval for survival probability: 0.00-0.00

*** This represents the confidence limit for one year survival probability for a population of patients with the characteristics listed above transplanted in the US between 2012 and 2014.
Data Back to Centers (DBtC)

- Originally introduced in 2009 to provide validated data to centers from CIBMTR Research Database
- Includes Pre-TED (2400), Pre-TED Disease (2402) and Post-TED (2450) data or equivalents from CRF forms:
  - FormsNet as well as legacy IBMTR & NMDP data (pre-December 2007)
  - Allogeneic and autologous transplant data
- Accessible on the CIBMTR Portal; refreshed quarterly
- Downloadable file in comma separated values (.csv) file
- >450 data downloads by 113 centers
- 2,095 unique visits by non-CIBMTR users
eDBtC (enhanced DBtC) using QlikView

- Launched in April 2016
- Complete redesign of DBtC
- Visualization of center analytics and descriptive statistics
  - ~ 200 most common/valuable key TED and CRF variables
  - ~ 60 predefined filters
- Logical organization of data in tabs
- Ad Hoc analysis – explore your data, including outcomes
- Data refreshed monthly
- Ability to export application source data to excel
- Continues to be incrementally enhanced with more features and data
Screenshot of the eDBtC Application
eDBtC: Key enhancements in 2017

• GVHD Prophylaxis Agents
  – Data and bar charts for common drug combinations
• Conditioning Regimen Agents
  – Data and bar charts by transplant type & conditioning regimen
• Sub-diseases
  – Ability to segment your population by sub-disease
  – Ability to see AML type (i.e. denovo, secondary, unknown)
• Data Download
  – Data download has become more user friendly with decoded datasets
  – Build Your Own Data Download (BYOD) enables users to create a customized, CRID-level data set by selecting and exporting data of interest to better manage ever expanding fields added to eDBtC
What have you used eDBtC for?

![Bar Chart]

- **Data Quality Checks/Internal Auditing**: 60%
- **Supplemental internal research (studies, assistance with mandatory reporting)**: 40%
- **To download data as an input for a database at my center**: 20%
- **Comparative analysis**: 20%
eDBtC: Looking ahead

• Anticipate more features and data in eDBtC
  – Incremental expansion of TED & CRF HCT data
  – Beginning to include Cellular Therapy (CT) data collected on CTED forms (4000, 4100, 4006…)
  – Continue to enhance data download functionality
Data for RFI

• Launched just after Tandem in 2017
• A solution (QlikView and Excel) for US-based centers to support completion of their ASBMT RFI to share outcomes data
• Provides centers with ability to access, view, reconcile, format and supplement their outcomes data
• Leverages eDBtC data, but translates data to the ASBMT standard formats and rules
• Data are refreshed monthly
Center Performance Analytics using QlikView

- Launched in April, 2016
- Intended to support center-based quality and performance management initiatives
- On-demand access to the same center specific analysis data set used to prepare your annual Center Specific Survival Analysis report
- Enables comparison of your center’s descriptive statistics with other centers based on similar characteristics
- Refreshed annually with the updated dataset, most recently in December 2017
Screenshot of CPA application
Which CIBMTR Portal Products have you used (check all that apply)?

- eDBtC (enhanced Data Back to Center)
- Data for RFI (Request for Information)
- CPA (Center Performance Analytics)
- Survival Calculator
- Center Volumes Data Report (U.S. only)
How did you learn the application(s)?

4.7% Other, please specify:
1.6% I watched a recorded presentation from the Tandem Data Managers meeting
8.4% I attended Tandem Data Managers meeting
12.0% I learned from a co-worker who uses the application(s)
2.6% I received training from a CIBMTR representative
51.3% I just started using the application(s)
19.4% I watched the tutorial
Describe your experience with the tools

Meets or Exceeds Expectations

- RFI
- eDBtC
- CPA
- Survival Calc
- CVDR
Ongoing feedback opportunities

• If you have additional questions or feedback for the Information Technology team after today’s presentation, feel free to reach out to your CRC.
  – Your CRC will pass the feedback to us, and we can reach out to you if desired as well.

• Annual FormsNet survey going forward
Questions?