Utah BMT Program at Huntsman Cancer Institute

Data Manager Training Manual

Data Management Team

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Welcome

Welcome to the Huntsman Cancer Institute BMT Program! This manual is meant to help guide you through your first few months in this position. There is a lot to learn - but with the guidance of this form and your new team, we know that you can do it.

The training checklist serves two purposes: it gives you an idea of the training timeline, which includes training that comes from your team as well as training that can be done on your own, and it serves to show the general expectations of knowledge along the way.

Many resources exist in the world of BMT, so the majority of the information provided in this manual is specific to Epic and how to navigate information that is pertinent to your position. Other resources will be provided as hyperlinks throughout the manual, but please do not hesitate to ask for additional sources of information as you feel necessary.

Training/Onboarding Checklist

Month One

- ☐ Complete hospital orientation
- ☐ Complete HCI orientation
- ☐ Complete onboarding with department Administrative Assistant.
- ☐ Complete LMS training modules, including Epic training modules.
    - o See page 5 for details.
- ☐ Complete Epic training.
    - o Epic user template should model BMT Coordinators and Quality Manager
- ☐ Read the following CPG's and SOP's:
    - o BMT CPG: ADM 1- BMT Program Scheduled Meetings

- BMT CPG: ADM 7- Data Reporting to CIBMTR and SCTOD
- BMT SOP: 002- Total Quality Management Plan

- ☐ Attend the allogeneic patient education class.
- ☐ Attend the autologous patient education class.
- ☐ Complete CITI training (Biomedical HSR and GCP) and submit documentation to Data Supervisor.
  - See page 5 for details
- ☐ Spend an hour a day reading in the 6th floor HCI Patient Resource Library.
- ☐ Spend an hour a day watching CIBMTR Training Videos and videos pertinent to transplant education, including Be The Match Transplant Basics
- ☐ Spend two hours a day shadowing someone working on auto 2400 forms (First week).
- ☐ Spend two hours a day shadowing someone working on auto 2402 forms (Second week).
- ☐ Spend two hours a day doing guided and solo practice on auto 2400 forms (these forms cannot be submitted without being reviewed by another member of the data management team) (Third week).
- ☐ Spend two hours a day doing guided and solo practice on auto 2402 forms (Fourth week).
- ☐ Train and work on forms 2804 and 2814.
- ☐ *By the end of month one, you should be able to complete forms 2804 and 2814 on your own*.

Month Two

- ☐ Read the following CPG's and SOP's:
  - BMT CPG: P 2-Mobilization and Collection for Peripheral Blood Stem Cell and Donor Lymphocyte Infusion
  - BMT CPG: PR 1- Standard Preparative Regimens for BMT and CAR T-cell Patients
  - BMT CPG: PS 1- Blood and Marrow Transplant Criteria
- ☐ Spend two hours a day shadowing someone working on allo 2400 and 2402 forms (First two weeks).
- ☐ Spend two hours a day doing guided and solo practice on allo 2400 and 2402 forms (these forms cannot be submitted without being reviewed by another member of the data management team). (First two weeks)
- ☐ Spend two hours a day shadowing someone working on auto 2450 forms (Second two weeks).
- ☐ Spend two hours a day doing guided and solo practice on auto 2450 forms (Second two weeks).
- ☐ Train on NMDP Biorepository Samples.
- ☐ Continue reading and watching videos as you feel necessary to understand topics related to transplant.
- ☐ Train and work on 2820 forms.
- ☐ *By the end of month two, you should be able to complete 2820 forms on your own.*

Month Three

- ☐ Read the following CPG's and SOP's:
  - BMT CPG: IM 1- Graft Failure/Rejection Definition
  - BMT CPG: IM 2- Engraftment Syndrome Following Blood and Marrow Transplant
  - BMT CPG: SC 5- Myeloid Growth Factors for Post-Transplant Reconstitution
- ☐ Work on current 2400 and 2402 forms.

- ☐ Spend two hours a day shadowing someone doing allo 2450 forms (First two weeks).
- ☐ Spend two hours a day doing guided and solo practice on allo 2450 forms (First two weeks).
- ☐ Spend two hours a day shadowing someone working on auto 2100 and 21XX forms (Second two weeks).
- ☐ Spend two hours a day doing guided and solo practice on auto 2100 and 21XX forms (these forms cannot be submitted without being reviewed by another member of the data management team) (Second two weeks).
- ☐ Work on current 2450 forms.
- ☐ Continue spending time reading and watching videos as you feel necessary to understand topics related to transplant.
- ☐ *By the end of month three, you should be able to send NMDP Biorepository Samples on your own.*
- ☐ *By the end of month three, you should be able to complete 2400's and 2402's on your own and they will be subject to audit.*

Month Four

- ☐ Read the following CPG's and SOP's:
    - BMT CPG: IC 1- Infection Prophylaxis
    - BMT CPG: IM 3- Acute Graft Versus Host Disease Prophylaxis, Evaluation and Management
    - BMT CPG: IM 4- Diagnosis and Management of Chronic Graft Versus Host Disease (cGVHD)
- ☐ Work on current forms that you are comfortable with (2804, 2814, 2820, 2400, 2402, 2450, auto 2100 and 21XX).
- ☐ Spend two hours a day shadowing someone working on allo 2100 and 21XX forms. (First week)
- ☐ Spend two hours a day doing guided and solo practice on allo 2100 and 21XX forms (these forms cannot be submitted without being reviewed by another member of the data management team) (Second week).
- ☐ Train on study specific forms in FormsNet3.
- ☐ Work on current 2100 and 21XX forms.
- ☐ *By the end of month four, you should be able to complete 2450's and 2100's on your own and they will be subject to audit.*
- ☐ *By the end of month four, you should be able to complete study forms in FormsNet3.*

Month Five

- ☐ Read the following CPG's and SOP's
    - BMT CPG: IM 5- Donor Lymphocyte Infusion for Relapsed Patients Post Transplant
    - BMT CPG: IM 6- Management of CAR-T Cell Toxicity
- ☐ Work on current forms that you are comfortable with (2804, 2814, 2820, 2400, 2402, 2450, 2100, 21XX).
- ☐ Spend two hours a day shadowing someone working on 2006 forms (to be completed in partnership with CTRM).
- ☐ Spend two hours a day doing guided and solo practice on 2006 forms (these forms cannot be submitted without being reviewed by another member of the data management team).

- ☐ Spend two hours a day shadowing someone working on 4000 and 4100 forms.
- ☐ Spend two hours a day doing guided and solo practice on 4000 and 4100 forms (not to be submitted without being checked).
- ☐ *By the end of month five, you should be able to complete disease specific forms 20XX, and 21XX on your own and they will be subject to audit.*

Month Six

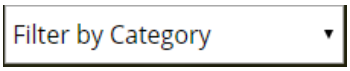
- ☐ Work on all current forms that you're comfortable with.
- ☐ Spend two hours a day shadowing someone working on 4003 and 4006 forms.
- ☐ Spend two hours a day doing guided and solo practice on 4003 and 4006 forms (not to be submitted without being checked).
- ☐ Spend two hours a day shadowing someone working on 2000 forms.
- ☐ Spend two hours a day doing guided and solo practice on 2000 forms (not to be submitted without being checked).
- ☐ Train on internal program database and outcome tracking.
- ☐ *By the end of month six you should be able to complete cell therapy forms and product forms 2006 on your own and they will be subject to audit.*
- ☐ *By the end of month six, you should be able to complete CTED forms and they will be subject to audit.*
- ☐ *By the end of month six, you should be able to assist with physician data requests and outcome tracking.*

Instructions for Trainings

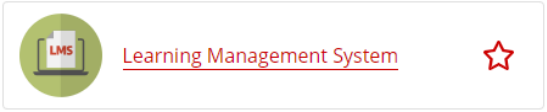
LMS Modules

- Epic – Some Epic training modules need to be completed before the class.
- Annual trainings are due by the end of March.

You can access your LMS Modules in one of two places. To access your LMS through your CIS page, go to cis.utah.edu and fill in your login information. Once you are in the CIS home page, you will see a drop down menu that looks like this:



There you will find the following tile:



Another place to access your learning modules is through PULSE at pulse.utah.edu. Here you will also have to sign in before you can find the following tile:

Please keep in mind that you will also have annual LMS training modules to complete. Each year you can access these training modules throught the same points of access.

Research Specific Trainings

- Create ERICA Account
  - https://irb.utah.edu/guidelines/erica-assistance/access-instructions-2.php
  - Department: 61663
- CITI Biomedical Human Subjects Research
- CITI Good Clinical Practice

Ongoing Trainings

- Continuing Medical Education – We are ***required*** by FACT to attend 10 hours of CME events each year. To set up your CME account, visit the following link:
  - https://medicine.utah.edu/cme/
  - Select 

and complete all required fields on the following page.
  - When you attend a CME credit event, make sure to sign in either by phone or online.
  - TCT – Transplantation and Cellular Therapies Meetings Of ASTCT And CIBMTR
    - Occur annually and can count toward your CME credits.
- CIBMTR Data Management Newsletters
  - You are required to read these quarterly.
    - Sent out February, May, August, and November.
  - They will be emailed but can also be accessed HERE.

Transplant 101

Healthy marrow and blood cells are needed to live. When disease affects marrow so that it cannot function properly, a marrow or cord blood transplant could be the best treatment option, and for some patients, offers the only potential cure.

Hematopoietic stem cell transplant is a procedure to replace cells that produce blood. The patient receives high doses of chemotherapy, radiation, or both, to kill cancer cells and healthy cells in the bone marrow where blood is formed. The patient then receives new blood-forming stem cells through an IV. Healthy blood cells develop from the transplanted stem cells.

Types of Transplant

Autologous

An autologous transplant is when a person's own hematopoietic stem cells are used. These cells are collected from the patient's bloodstream and stored for transplant.

Allogeneic

An allogeneic transplant is when hematopoietic stem cells from a family member, unrelated donor or umbilical cord blood unit are used for transplant

Treatment/Drug Timeline

The following is an example of therapy timeline. Keep in mind that everyone's timeline is not necessarily the same.

- Induction – the first treatment given to a patient after diagnosis.
- Consolidation – given to ensure that all remaining cancer cells are still being treated, even in low level or minimal residual disease.
- Preparative Regimen/Conditioning – the drugs given just before going into transplant and is meant to kill the patient's diseased cells and/or make room in their bone marrow for healthy blood stem cells.
- Maintenance – drugs and other therapies given to keep the patient's disease and/or disease burden under control.
- Possible non-drug therapies – radiation, surgical resection.

Complications

GVHD

- Occurs in allogeneic patients.
- GVHD happens when the cells from the donor (the graft) see the recipient's body's cells (the host) as different and attack them. There are medicines to help lower the risk of getting GVHD. But even with medicine, some people still get GVHD. GVHD can range from mild to severe. Many patients will have some symptoms of GVHD after transplant.
- Acute: Typically develops in the early weeks and months after transplant. It's called Late Acute GVHD when it develops 3 or more months after transplant.
- Chronic: Typically develops within 1 year of transplant. It's called Overlap Chronic GVHD when signs and symptoms of chronic and acute GVHD appear together.
- See appendix for worksheets on acute and chronic GVHD.
    - REPORTING GVHD MUST BE DONE USING THESE WORKSHEETS. Reviewed in Q+A.
        - File Explorer
        - Hscgroups
        - BMT Quality Path
        - Training and Information for DM

        - "Acute GVHD WS"
        - "Chronic GVHD WS"
    - Always refer to the CIBMTR Manual when reporting GVHD.
        - Form 2450 GVHD Forms Instruction Manual
        - Form 2100 Acute GVHD Forms Instruction Manual
        - Form 2100 Chronic GVHD Forms Instruction Manual

Infection

Since the recipient's immune system is weak, they are at a greater risk for infections. For this reason, transplant patients receive certain drugs for antimicrobial prophylaxis.

Graft failure

Graft failure happens when the recipient's bone marrow does not accept the donor's hematopoietic stem cells as it should. There is usually some degree of bone marrow failure. Generally, graft failure is followed by another transplant.

CAR-T Cells and Other Immunotherapy

- Chimeric antigen receptor (CAR) T cell therapy is a treatment for some types of cancer. Our program typically uses CAR-T therapy for some types of leukemia and lymphoma.
- T cells are part of your immune system. They work by "hooking" onto cancer cells and killing them. In CAR T cell therapy, doctors take T cells from your blood and add a new "hook" called a CAR to them. Together, these are called CAR T cells. You get the CAR T cells back through an infusion into a vein. The CAR T cells find, attack, and kill the cancer cells in your body.
- Other immunotherapies are used throughout oncology. You will be educated and trained on these as it becomes applicable to your role.

FACT and CIBMTR

Accreditation Information

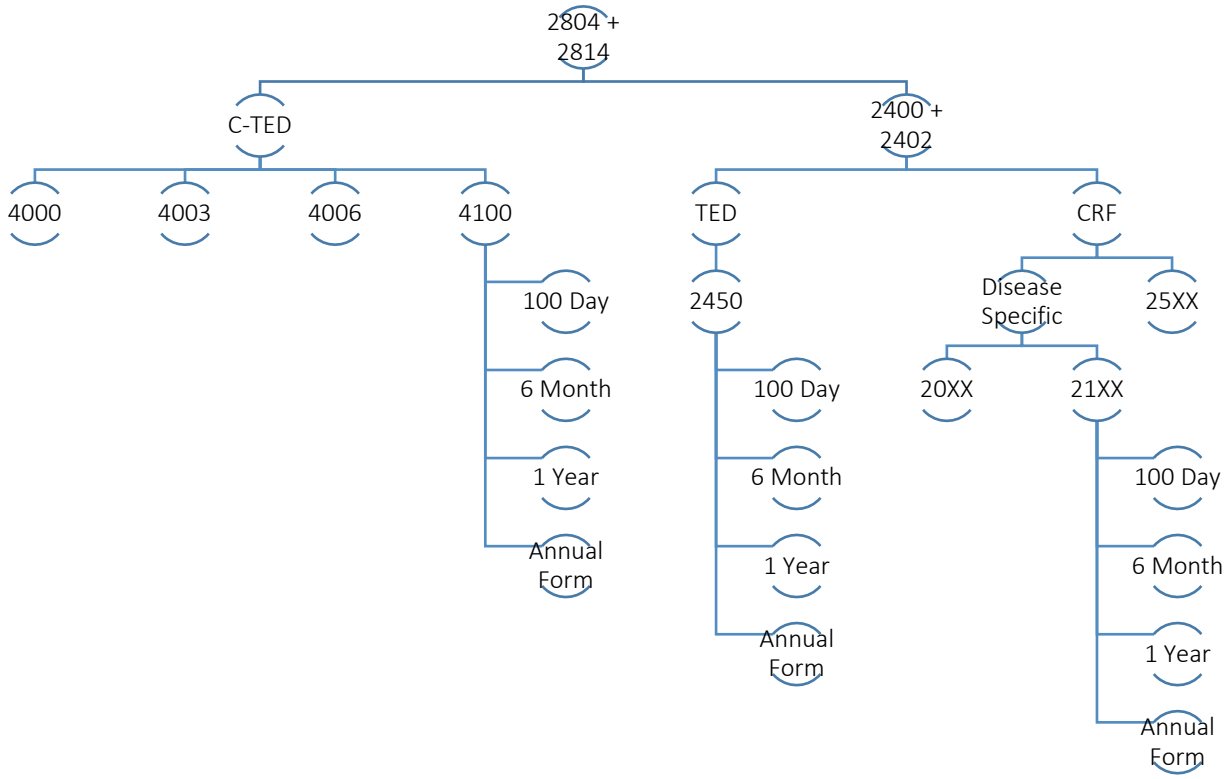
- FACT – Foundation for the Accreditation of Cellular Therapy
    - FACT is the primary accrediting body for Hematopoietic Stem Cell Transplant and Cellular Therapy programs.
    - A program must renew its FACT accreditation every three years. At the time of renewal, programs are subject to an onsite inspection by FACT. Inspectors review a program's policies and practices to ensure compliance with FACT standards
    - Many insurance companies negotiate contracts and reimbursement based on a program's accreditation status, meaning FACT accreditation has significant implications and consequences for the program and the university.
- CIBMTR – Center for International Blood & Marrow Transplant Research
    - FACT and CIBMTR operate a collaborative program for quality in data management. CIBMTR audits a center's data management program every 4 years. Passing CIBMTR audits is directly linked to a center's FACT accreditation.

- Data Management Quality is governed by Section B9 of the FACT Clinical Program Standards.
- To pass a CIBMTR Data Management Audit, programs must achieve ≤ 3% critical field error rate in their CIBMTR onsite data audit.
    - Programs with >3.0% critical field error rate will fail the CIBMTR Data Audit and be required to submit corrective action plans and follow up reports to the FACT-CIBMTR Data Audit Committee to maintain their FACT Accreditation.
    - Following a second consecutive CIBMTR Data Audit failure, the program's FACT accreditation may be suspended. Reaccreditation will require a passing CIBMTR Data Audit and may require a reinspection by FACT outside the standard 3-year cycle.
    - Additional consequences of two consecutive failed data audits are:
        - Site data may not be included in the Center Specific Outcomes national average calculation
        - The site may be identified on the Center Specific Outcomes website as a center that has not met data quality requirements
        - Site data may be quarantined from research activities with CIBMTR; data will remain quarantined from research studies until the next scheduled audit date, unless the center pays for an additional audit prior to that time
        - The site may be changed to a Transplant Essential Data (TED) only reporting center, removing it from the network of transplant centers that complete research forms. Research forms are required for centers participating in CMS CED studies that guarantee Medicare reimbursement for patients transplanted for certain conditions
        - Transplant center scientists and staff cannot participate in CIBMTR leadership roles or as members of CIBMTR administrative committees

CIBMTR Center Information:

Center Number: 10192
Center Name: Utah Blood and Marrow Transplant Program – Adults

FormsNet3 Forms Outline



TED = Transplant Essential Data
CRF = Comprehensive Report Form
C-TED = Cell Therapy Essential Data

Form Specific and Common Disease Guide

2400 – Pre-Transplant Essential Data (Pre-TED)

2400 Forms Instruction Manual

*Keep in mind that the patient may have a lot of their medical history and disease history in outside media. To access a patient's outside records you can go to:

a. Chart Review
b. Media
c. Care Everywhere

- **Demographic Information** (This will be auto-populated from the CRID assignment, however it is a critical field and should always be verified correct.)
    - Chart Review
    - Snapshot
    - Demographics
- **Blood Type**
    - Chart Review

- Labs/Path/Micro
  - Filters
  - Select “ABO-RH TYPE AUTOMATED”.

- CMV Status
  - Look for the
    - CMV IgG Lab
    - NMDP panel
      - If the patient has ANY history of positivity in these labs, report them as reactive/positive, UNLESS there is documentation in physician notes that it is a false positive. If you have any questions consult another data manager.
    - Do NOT use CMV/PCR or CMV QUANTITATIVE labs for this question.
- Consents
  - File Explorer
  - (S) Drive
  - hscgroups
  - BMT COORDS
  - SCANNED CHART DOCUMENTS
  - (transplant year)
  - (patient name)
  - If donor consents are needed, they will be in a folder under the recipient’s name.
    - OR, in Epic:
    - Chart Review
    - Media
    - Document Management
    - Consents
  - Look for CIBMTR consents. Be sure to check off the following items before you continue:
    - Make sure consents are in the EMR, scanned internal documents, AND in physical form.
    - Make sure the dates match between the person signing and the person consenting. If they do not match, report it to Kayla.
    - Make sure the person signing also selected “yes” for future research. If they did not, report it to Kayla.
    - Make sure all applicable fields are completed (i.e. printed name line not filled out).
- Research Studies
  - Beaker icon in small bubble to the right of patient’s photo. Look for studies with:
    - RCI BMT (Resource for Clinical Investigation in Blood and Marrow Transplantation). Prospective research.
    - BMT CTN (Blood and Marrow Transplant Clinical Trials Network).
    - USIDNET (United States Immunodeficiency Network).
    - COG (Children’s Oncology Group).

        - Other sponsor.
            - It's better to over-report than to under-report! When in doubt, don't hesitate to ask.

- HCT and Cellular Therapy
    - ALWAYS verify the date of HCT. To verify, look for a procedure note within notes. If the date of the transplant is different than what is reported, then it must be corrected in form 2814 (Indication Form).
        - Also report it to the coordinators to update the BMT Evaluation Summary.
    - To find out if a patient has had a prior HCT or if there is a plan to perform a subsequent HCT, simply read through progress notes. The minimum recommendation is to read the progress note when the patient was first seen, read one or two between the first note and the last note before transplant, and read the last note before transplant. This should provide enough information so that you can understand the history, timeline, and plan for this patient.
- Donor Information
    - You can use the BMT Evaluation Summary as a starting point for the answers to these questions, however they still need to be verified:
        - The donor will have an MRN listed on the recipient's BMT Evaluation Summary or you can access donor information in the recipient's CTRM chart:
            - File Explorer
            - (S) Drive
            - hscgroups
            - Cell Therapy Patients
            - Patient Folders
            - (patient name)
    - HLA documents can be found:
        - Chart Review
        - Media
        - Or:
            - File Explorer
            - Hscgroups
            - BMT COORDS
            - HLA & PRA
            - Patient Last Name
- Mobilization
    - To find source documentation of which drugs were used to mobilize, simply search each drug into the Epic search bar. Check the Medication Administration Record (MAR). In the MAR, you will verify a few things:
        - The dates should match up with the dates of the mobilization. Some drugs are used for other indications, so the presence of the drug in the MAR does not automatically mean that it was used for mobilization.

        - Verify that the medication was administered. If you select the drug, and scroll down about halfway, you will find a blue link that reads “Full Administration Report”. If you see this, it means that the drug was administered. If you click on it, you can see specific details about amount, date, and time administered. If this is not seen, that means it was NOT given and should not be reported.
        - Checking the patient’s mobilization and collection calendar within their CTRM chart can serve as a guide to find dates, planned drugs, and to check if chemotherapy was planned to be a part of their mobilization process.
- Clinical status
    - Search “Karnofsky” or “KPS”. Always look for the last date reported BEFORE the beginning of the preparative regimen. If there is a score on the same day the first preparative regimen drug was given, choose the date before since the patient could have already received the drug by the time they were seen by the physician.
- Comorbid Conditions
    - Again, the BMT Evaluation Summary can serve as a starting off point for reporting, however everything needs to be verified as the BMT Evaluation Summary is not source documentation. Always be sure to have Appendix J - Reporting Comorbidities in the CIBMTR Manual open to ensure proper reporting. To ensure a thorough search within Epic, use the following tips:
        - Mechanical ventilation → search “mechanical ventilation”, “intubation”, and “life support”.
        - Fungal infection → search “fungal infection” and “fungemia”.
        - Arrhythmia → search “arrhythmia”, “flutter”, and “sick sinus syndrome”.
        - Cardiac → search “coronary artery disease”, “stent”, “congestive heart failure”, “myocardial infarction”. Also be sure to check the most recent echocardiogram, and verify that the ejection fraction (LVEF) is above 50%.
        - Cerebrovascular disease → search “cerebrovascular disease”, “transient ischemic attack”, “subarachnoid hemorrhage”, “cerebral thrombosis”, “cerebral embolism”, and “cerebral hemorrhage”.
        - Diabetes → search “diabetes”.
        - Heart valve disease → search “heart valve”. Check the most recent echocardiogram summary and impression at the bottom of the report. If there are any valvular abnormalities it will be noted here. If abnormalities are present compare with CIBMTR Manual to determine if it’s reportable.
        - Hepatic, mild → search “hepatitis” and check the labs that come up for positive results. Then go to labs/path/micro and select “BASIC METABOLIC PANEL” and “COMPREHENSIVE METABOLIC PANEL”, and “HEPATIC FUNCTION PANEL” (HFP is rarely done). Filter the dates to from day -24 through the start of the preparative regimen. You will be looking at the numbers for bilirubin, AST, and ALT.
        - Hepatic, moderate / severe → Keep the same lab inquiry open and check the criteria for bilirubin, AST, and ALT.

        - Infection → search “infection”. Concentrate your search to the few days before and going into transplant. If there are any questions about reporting infection, bring it to Q+A.
        - Inflammatory bowel disease → search “inflammatory bowel disease”, “Crohn’s”, and “ulcerative colitis”.
        - Obesity → check the patient’s height and weight on the first med of the preparative regimen. Open a BMI calculator on the internet and input the height and weight.
        - Peptic Ulcer → search “ulcer”.
        - Psychiatric disturbance → search “anxiety” and “depression”.
        - Pulmonary, moderate → search “pft” and find the pulmonary function test that is under the “procedures” tab. Check the “FEV1” and the corrected diffusion capacity (DLCOHb). Make sure there are no notes about difficulty breathing in the notes going into transplant.
        - Pulmonary, severe → Do the same as pulmonary, moderate.
        - Renal, moderate/severe → pull up metabolic panel labs the same way you did for hepatic, except this time you are looking for creatinine. Search “kidney transplant”.
        - Rheumatologic → search “arthritis” (and make sure only to report instances of rheumatoid arthritis. If it is not specified in the history, it can safely be assumed that it is NOT rheumatoid and therefore should not be reported). Search “lupus”.
        - Prior malignancy → prior malignancies will be noted in the patient’s history.
- Biomarkers
    - Chart Review
    - Labs/Path/Micro
        - Filter:
        - BASIC METABOLIC PANEL
        - COMPREHENSIVE METABOLIC PANEL
        - All “CBC” check boxes
        - FERRITIN
        - MANUAL DIFFERENTIAL
        - Make sure to filter dates as specified in the form’s questions.
- Preparative Regimen
    - Use the BMT Evaluation Summary and progress notes to identify which drugs are planned for preparative regimen. Then simply search each drug in Epic to find it in the MAR.
    - Height and Weight can be found in the first administered drug of the preparative regimen. Be sure that the weight is the patient’s “actual” weight, not their “dosing” weight.
    - The BMT Evaluation Summary will state if a prep-regimen is myeloablative (for allogeneic transplants). Again, be sure to verify the drugs and dosing with the CIBMTR manual.
    - To look for radiation dosing search “cGy”. Make sure to look at the note from the radiology doctor who administered the radiation.
    - Make sure to report ALL drugs prescribed in the preparative regimen.

        - Pharmacokinetics: remember that some drugs (i.e. busulfan) may have multiple orders in the MAR as a result of pharmacokinetics. Be sure to report the prescribed dose.
- Other drugs
    - Any other drugs that would be asked about in the form can simply be searched in Epic. If there is a result in "meds" and you have verified administration in the MAR, then report "yes".
    - Prophylactic drugs- these are drugs given to PREVENT a disease, condition, reaction, infection, etc. (including prophylaxis for GVHD, infection, etc.)

2402 – Disease Classification (guide for common diseases).

2402 Forms Instruction Manual

- AML – Acute Myelogenous Leukemia
    - AML Classification – this will be listed on the BMT Evaluation Summary and the Physician Worksheet. However, this needs to be verified. To verify, you can check cytogenetic results, molecular testing results, bone marrow pathology results, radiology results, and physician notes. If you have any questions, consult another data manager.
    - Information about the patient's disease timeline, transformation and history can be found in the progress notes.
    - Labs:
        - Chart Review
        - Labs/Path/Micro
        - Select the following boxes if present:
            - ACUTE MYELOID LEUKEMIA PANEL BY FISH
            - CHROMOSOME ANALYSIS…
            - CHROMOSOME FISH-INTERPHASE
            - FLT3 ITD AND TKD MUTATION DETECTION
            - MYELOID MALIGNANCIES MUTATION PANEL NGS
            - LEUK/LYMPH PHENOTYPING, FLOW CYTOMETRY
            - PATHOLOGY REPORTS – Select each one listed
            - PML-RARA TRANSLOCATION BY FISH
                - There may be more tests that come out as time goes on. Check with data supervisor as needed.
                - If a patient has a history of having a specific molecular marker, they may have labs specific to that marker. Check for this.
    - Keep in mind that this section of the form will ask for labs at diagnosis, between diagnosis and last evaluation, and at the last evaluation prior to transplant. You will have to find the dates for all applicable time frames.
    - When reporting complex cytogenetics, be sure to create a pdf document with the results from the cytogenetic reports and attach it to the form you are working on.

- When reporting the molecular testing results, **always** attach a pdf document with the results to the form you are working on.
- Disease status:
  - This will be listed on the BMT Evaluation Summary and the Physician Worksheet. However, this needs to be verified. This can be verified by checking the diagnostic criteria listed in the CIBMTR's AML Response Criteria.
  - Make sure that the "date assessed" always reflects the last date that pertinent diagnostic testing was performed.

- Acute Lymphoblastic Leukemia (ALL)
  - Specify ALL classification: This will be listed on the BMT Evaluation Summary and the Physician Worksheet. However, this **needs** to be verified. To verify, you can check cytogenetic results, molecular testing results, bone marrow pathology results, radiology results, and physician notes. If you have any questions, consult another data manager.
  - Information about the timeline and transformation of the disease can be found in progress notes of a BMT/Hematology provider.
  - Labs:
    - Chart Review
    - Labs/Path/Micro
    - Select the following boxes, if listed:
      - B-ALL MRD BY FLOW CYTOMETY
      - BCR-ABL1 Tests – Select each one listed
      - CHROMOSOME ANALYSIS – Select all tests with "Chromosome"
      - CHROMOSOME FISH-INTERPHASE
      - LEUK/LYMPH PHENOTYPING BY FLOW CYTOMETRY
      - MYELOID MALIGNANCIES MUTATION PANEL NGS
      - PATHOLOGY REPORTS – Select each one listed
      - PH-LIKE ALL PANEL BY FISH
  - Keep in mind that this section of the form will ask for labs at diagnosis, between diagnosis and last evaluation, and at the last evaluation prior to transplant. You will have to find out the dates of the first and last evaluation and be sure to filter the dates for each time frame.
  - When reporting complex cytogenetics, be sure to create a pdf document with the results from the cytogenetic reports and attach it to the form you are working on.
  - When reporting the molecular testing results, always attach a pdf document with the results to the form you are working on.
  - Status at transplantation: Verify patient's status at transplant by checking the diagnostic criteria listed in the CIBMTR's ALL Response Criteria. Make sure that the "date assessed" always reflects the last date that pertinent diagnostic testing was performed.
- MDS – Myelodysplastic/Myeloproliferative Diseases
  - Subtype at diagnosis: This will be listed on the BMT Evaluation Summary and the Physician Worksheet. However, this **needs** to be verified. To verify, you can check

cytogenetic results, molecular testing results, bone marrow pathology results, radiology results (i.e. PET CT), and physician notes. If you have any questions, consult another data manager.

- Information about the timeline and transformation of the disease can be found in progress notes of a BMT/Hematology provider.
- Labs:
  - Chart Review
  - Labs/Path/Micro
  - Select the following boxes, if listed:
  - CBC'S and MANUAL DIFFERENTIAL
    - Select all results from these lab tests within the appropriate timeline, and click "lab flowsheet".
  - PATHOLOGY REPORTS
  - CHROMOSOME ANALYSIS
  - CHROMOSOME FISH-INTERPHASE
  - FLT3 ITD AND TKD MUTATION DETECTION
  - MYELOID MALIGNANCIES MUTATION PANEL NGS
  - MDS PANEL BY FISH
  - ACUTE MYELOID LEUKEMIA PANEL BY FISH
  - LEUK/LYMPH PHENOTYPING, FLOW CYTOMETRY
- Keep in mind that this section of the form will ask for labs at diagnosis, between diagnosis and last evaluation, and at the last evaluation prior to transplant. You will have to find out the dates of the first and last evaluation and be sure to filter the dates for each time frame.
- When reporting complex cytogenetics, be sure to create a pdf document with the results from the cytogenetic reports and attach it to the form you are working on.
- Disease status at transplantation:
  - This will be listed on the BMT Evaluation Summary and the Physician Worksheet. However, this needs to be verified. This can be verified by checking the diagnostic criteria listed in the CIBMTR's MDS/MPN Response Criteria.
  - Make sure that the "date assessed" always reflects the last date that pertinent diagnostic testing was performed.

- Hodgkin and Non-Hodgkin Lymphoma (NHL)
  - You are going to see more Non-Hodgkin Lymphomas than Hodgkin Lymphomas.
  - Specify lymphoma histology: This will be listed on the BMT Evaluation Summary and the Physician Form. However, this needs to be verified. To verify, you can check bone marrow or lymph node pathology results, radiology results, and spinal taps (rare).
  - Information about the timeline and transformation of the disease can be found in progress notes/history of present illness.
    - PATHOLOGY
    - PET/CT
    - CT

        - MRI
        - LEUK/LYMPH PHENOTYPING BY FLOW
    - **Status at transplant:** This will be listed on the BMT Evaluation Summary and the Physician Worksheet. However, this needs to be verified. This can be verified by checking the diagnostic criteria listed in the CIBMTR's Lymphoma Response Criteria.
    - **Lines of therapy:** You can get an idea of the number of lines of therapy given by reading progress notes under history of present illness. There will often be a timeline of events that map out the treatment history. To verify:
        - Chart Review
        - SnapShot
        - Springboard Report – This report will show the current treatment plan, but past treatment plans can be found if you scroll to the bottom of the screen.
- Multiple Myeloma / Plasma Cell Disorder
    - **Specify the multiple myeloma/plasma cell disorder:** This will be listed on the BMT Evaluation Summary and the Physician Worksheet. However, this **needs** to be verified. To verify, you can check cytogenetic results, molecular testing results, pathology results, radiology, immunoelectrophoresis results, and kappa/lambda ratio results. If you have any questions, consult another data manager.
    - **Specify heavy and light chain type/amyloidosis classification:** Same as above.
    - **Durie-Salmon staging:** This needs to be verified by looking at the following labs at diagnosis:
        - BASIC METABOLIC PANEL
        - COMPREHENSIVE METABOLIC PANEL
        - CBC'S
        - MANUAL DIFFERENTIAL
        - PATHOLOGY BONE MARROW
        - LEUK/LYMPH PHENOTYPING, FLOW CYTOMETRY
        - IMMUNOELECTROPHORESIS
        - BJPROTEIN QNT W/RFLX K/L FLC W RATIO
        - KAPPA/LAMBDA QNT
        - PET CT
        - CT
        - MRI
            - You will need to find all pertinent lab values and make sure that you select the appropriate Durie-Salmon staging. To organize these lab values, utilize the **multiple myeloma tracking sheet**.
                - File Explorer
                - Hscgroups
                - BMT Quality Path
                - Training and Information for DM
                    - "MM Dis Stat WS"

- Any information about the timeline of the patient's disease can be found in progress notes under history of present illness or under past medical history. If there are any questions about definitions or dates, consult another data manager for help.
- Labs at diagnosis:
  - Go to the same lab results as listed above, but include:
    - LACTATE DEHYDROGENASE, PLASMA OR SERUM
    - CHROMOSOME ANALYSIS BONE MARROW
    - MULTIPLE MYELOMA PANEL BY FISH
      - Once again, if cytogenetics have complex results, report what you can in the form and be sure to attach a PDF of the results.
- ISS and R-ISS Staging at diagnosis:
  - This information will likely be listed on the BMT Evaluation Summary, the patient's medical history, and on the physician form. To verify, look at the Basic and Comprehensive Metabolic Panel for the Serum B2-Microglobulin and serum albumin values and cytogenetic results. Always refer to the CIBMTR Manual for staging. If you have questions, consult another data manager.
- Status at transplantation:
  - This will be listed on the BMT Evaluation Summary, the patient's medical history, and on the physician form. To verify, pull up the CIBMTR Multiple Myeloma Response Criteria and compare the labs at last evaluation before transplant to the response criteria.
  - Make sure that the "date assessed" reflects the most recent testing pertinent to the diagnosis before transplant.

2450 – Post-Transplant Essential Data

2450 Forms Instruction Manual

- REPORTING PERIOD:
  - Data post-transplant is reported in "reporting periods" to capture data at 100 days, 6 months, and annually post-transplant.
  - Each form's reporting period STARTS the day AFTER the previous form's date of contact. Keep in mind that "date of contact" may not always be an office visit.
  - Once you determine the reporting period dates, filter by date the ***Encounter, Notes, Lab/Path/Micro and Imaging*** tabs.
- **Date of contact**: To determine an appropriate date for each reporting period, you can use a date calculator online. Simply enter the date of the transplant and add the appropriate time (i.e. 100 days, 6 months, 1 year) to that date.
- **Survival Status:** If the patient has died since the previous reporting period, the date of contact becomes the date of patient's death. The cause of death *might* be found in Epic:
  - Chart Review
  - Media
  - "Record of Death"

        - If a Record of Death is not found, the patient may have passed away outside of our hospital. In this case, consult another data manager on how to report the cause of death, as each situation will be different.
- Information about subsequent transplant (and other information about the patient's treatment timeline) can be found in a progress note written by a BMT/Hematology provider. Look under history of present illness and/or interim history section of the note.
- ANC and Platelet Recovery:
    - Chart Review
    - Labs/Path/Micro
        - Set date filter to reflect the current reporting period.
        - Select all CBC'S
        - MANUAL DIFFERENTIAL
    - Select the first result. Press the "Shift" button while selecting the last result. Select "Lab Flowsheet".
- For ANC recovery: you are looking for the Absolute Neutrophil Count.
    - Tip: you will notice it may take a few days after transplant for these numbers to drop. You are looking to report the first date of three consecutive ANC values ≥ 500/mm^3.
    - Tip: just because you see three values doesn't mean that all three fell on different days. Make sure that each value was observed on different dates.
    - ALWAYS make sure to check and see if graft failure occurred in every reporting period.
- For Platelet Recovery: first check to see when the patient's last platelet transfusion was. To do this:
    - Search "transfuse" in the search bar in Epic.
    - Select the results under "Other Orders".
    - Select any "Transfuse Platelets" order. You will be able to see the dates and times that the patient was administered platelets.
    - Take that date, enter it into a date calculator, and add 7 days.
        - YOU CANNOT REPORT A PLATELET RECOVERY BEFORE THIS DAY.
- Look for the first date of three where the patient's platelet levels are greater than or equal to 20x10^9 L.
- In rare cases, a patient may achieve platelet engraftment and become transfusion dependent again. Make sure you check for gaps in transfusions where engraftment counts may have been reached. For help with this, ask your data supervisor.
- Graft vs. Host Disease
    - GVHD will be mentioned in the progress notes of allogeneic patients in any of the following sections:
        - Under history of present illness
        - Interim history
        - Physical exam
        - Assessment/plan

    - To easily find the dates and descriptions of GVHD, simply search "GVHD" in Epic. Go through the results one by one and use that information with the GVHD flowsheets to verify all diagnostic criteria.
        - For acute GVHD flowsheet, see appendix C.
        - For chronic GVHD flowsheet, see appendix D.
    - We ALWAYS USE THE FLOWSHEETS alongside the CIBMTR Manual to report GVHD.
    - Bring GVHD reporting and flowsheets to Q+A.
- Liver toxicity prophylaxis: simply search each drug in Epic. If one comes up, verify that it was given in the time frame you are reporting and that it was used as a prophylaxis, not a treatment for something else. The drugs used most often at HCH are Defibrotide or Ursodiol, however that does not mean that the others are not used.
    - Tip: Tissue plasminogen activator (TPA) will often come up in the EMR as it is used to flush lines. If you have any question about the use, consult another data manager, although it is very unlikely it will be used for VOD prophylaxis.
- VOD – search VOD and SOS.
- New malignancies – if a new malignancy occurred, it would definitely be listed in the patient's progress notes, interim history, or medical history.
- Best response to HCT:
    - IF the patient was in Complete Remission (CR) at transplant, this will always be reported as "CCR".
        - If the patient was not in a CR at transplant, but achieved a CR in your reporting period, you will mark "Complete Remission" and note the date the CR was achieved. You will then be prompted to answer the rest of the questions in this section. Refer to the 2402 instructions for the list of diagnostic testing for the disease you are reporting on.
    - NOTE: Once a patient has achieved a CR, the Best Response to HCT on subsequent 2450 forms will be CR, and that the date of best response was previously reported.
- Post-HCT therapy:
    - This is therapy that was given for maintenance, not for relapse, persistent or progressive disease. These drugs will usually be mentioned in the History of present illness, Interim History section and/or in the "Assessment" section of the provider notes.
    - To verify that the drug was given and what it was given for, you can either search each drug and verify that the dates in the MAR match, or you can:
        - Chart Review
        - SnapShot
        - Springboard Report: The springboard report will show the current treatment plan, but past treatment plans can be found if you scroll to the bottom of the screen.
- Relapse or Progression:

- If the patient relapsed or had disease progression, the provider will note this in the progress notes under history of present illness, interim history, or even in the assessment/plan. Of course, it will need to be verified.
    - For a list of disease specific assessments, go to the 2402 instructions and look at the lists of diagnostic testing.

Current disease status:

- Determine the disease status of the patient on the contact date for the report you are working on.
- When reporting the "Date Assessed", use the most recent date of the test that is most pertinent for the disease you are reporting on.

2100 – Post-HCT Follow-Up Data

2100 Forms Instruction Manual

- REPORTING PERIOD:
    - Data post-transplant is reported in "reporting periods" to capture data at 100 days, 6 months, and annually post-transplant.
    - Each form's reporting period STARTS the day AFTER the previous form's date of contact. Keep in mind that "date of contact" may not always be an office visit.
    - Once you determine the reporting period dates, filter by date the ***Encounter, Notes, Lab/Path/Micro and Imaging*** tabs.
- Hematologic Findings – Click ***Lab/Path/Micro*** tab. In the Filter box, select the most recent tests for Comprehensive Metabolic Panel, Manual Differential and ***ALL*** CBC tests. Select all of these with the most recent date (Manual Differential may be older than the other tests) and create a lab flowsheet.**
    - Note: if a form asks for Neutrophils, this is usually called "Polymorphonuclear" or PMN on the flowsheet.
    - To see if patient had a recent transfusion, in search box, type "Transfusion", click 'Other Orders' and select any 'Transfuse RBC/Transfuse Platelets'. This will allow you search the dates of last transfusion to help you answer questions in this section.
- Immune Reconstitution – Follow the same process in item 1, however, select all "Immunoglobulin Serum (Ser, Seru…)" tests to find the results. If findings for IgG, IgM, IgA, etc. are not listed, mark as 'unknown'.
- Lymphocyte analyses – Follow the same process in item 1, however, select "Lymphocyte Subset Panel". Consult with a current Data Manager on how to report these findings on this form as there are a few ways to interpret the findings. Keep in mind that if this test is not listed, then this analyses was not done.
- Chimerism Studies – Follow the same process in item 1, however, select all Chimerism tests. This tests can be tricky, so work with a Data Manager to interpret and report these findings on this form.

2110 – Acute Myelogenous Leukemia (AML) Post-Infusion Data

2110 Forms Instruction Manual

For all 21XX forms, use the same reporting period as the corresponding 2100 form

- Disease Assessment at Time of Best Response
    - IF the patient was in Complete Remission (CR) at transplant, this will always be reported as "CCR".
        - If the patient was not in a CR at transplant, but achieved a CR in your reporting period, you will mark "Complete Remission" and note the date the CR was achieved. You will then be prompted to answer the rest of the questions in this section. Refer to the 2402 instructions for the list of diagnostic testing for the disease you are reporting on.
    - NOTE: Once a patient has achieved a CR, the Best Response to HCT on subsequent 2450 forms will be CR, and that the date of best response was previously reported.
- Post- HCT Therapy
    - This is therapy that was given for maintenance, not for relapse, persistent or progressive disease. These drugs will usually be mentioned in the History of present illness, Interim History section and/or in the "Assessment" section of the provider notes.
    - To verify that the drug was given and what it was given for, you can either search each drug and verify that the dates in the MAR match, or you can:
        - Chart Review
        - SnapShot
        - Springboard Report: The springboard report will show the current treatment plan, but past treatment plans can be found if you scroll to the bottom of the screen.
- Disease Detection
    - Look for the following labs/tests:
        - ACUTE MYELOID LEUKEMIA PANEL BY FISH
        - CHROMOSOME ANALYSIS…
        - CHROMOSOME FISH-INTERPHASE
        - FLT3 ITD AND TKD MUTATION DETECTION
        - MYELOID MALIGNANCIES MUTATION PANEL NGS
        - LEUK/LYMPH PHENOTYPING, FLOW CYTOMETRY
        - PATHOLOGY REPORTS – Select each one listed
        - PML-RARA TRANSLOCATION BY FISH
- Disease Status
    - This section will ask for results from molecular marker testing, cytogenetics, and hematologic findings. Look for the same labs/tests as above.
        - Make sure that the "date assessed" reflects the most recent testing pertinent to AML before transplant.

2111 – Acute Lymphoblastic Leukemia (ALL) Post-Infusion Data

2111 Forms Instruction Manual

For all 21XX forms, use the same reporting period as the corresponding 2100 form

- Disease Assessment at Time of Best Response
    - IF the patient was in Complete Remission (CR) at transplant, this will always be reported as "CCR".
        - If the patient was not in a CR at transplant, but achieved their FIRST CR post-transplant in your reporting period, you will mark "Complete Remission" and note the date the CR was achieved. You will then be prompted to answer the rest of the questions in this section.
            - Refer to the 2402 instructions (page 15) for the lists of diagnostic testing for the disease you are reporting on.
    - NOTE: Once a patient has achieved a CR, the Best Response to HCT on subsequent 2450 forms will be CR, and that the date of best response was previously reported.
- Post- HCT Therapy
    - This is therapy that was given for maintenance, not for relapse, persistent or progressive disease. These drugs will usually be mentioned in the History of present illness, Interim History section and/or in the "Assessment" section of the provider notes.
    - To verify that the drug was given and what it was given for, you can either search each drug and verify that the dates in the MAR match, or you can:
        - Chart Review
        - SnapShot
        - Springboard Report: The springboard report will show the current treatment plan, but past treatment plans can be found if you scroll to the bottom of the screen.
            - Common maintenance in ALL: intrathecal methotrexate or tyrosine kinase inhibitors such as dasatanib.
                - This is not comprehensive, and the treatment should still be verified.
- Disease Detection
    - Look for the following labs/tests:
        - B-ALL MRD BY FLOW CYTOMETY
        - BCR-ABL1 Tests – Select each one listed
        - CHROMOSOME ANALYSIS – Select all tests with "Chromosome"
        - CHROMOSOME FISH-INTERPHASE
        - FLT3 ITD AND TKD MUTATION DETECTION
        - LEUK/LYMPH PHENOTYPING BY FLOW CYTOMETRY
        - MYELOID MALIGNANCIES MUTATION PANEL NGS
        - PATHOLOGY REPORTS – Select each one listed
        - PH-LIKE ALL PANEL BY FISH
- Disease Status
    - This section will ask for results from molecular marker testing, cytogenetics, and hematologic findings. Look for the same labs/tests as above.
        - Make sure that the "date assessed" reflects the most recent testing pertinent to ALL before transplant.

2114 – Myelodysplasia/Myeloproliferative Neoplasms (MDS/MPN) Post-HCT Data

2114 Forms Manual

For all 21XX forms, use the same reporting period as the corresponding 2100 form

- Disease Assessment at Time of Best Response
  - IF the patient was in Complete Remission (CR) at transplant, this will always be reported as "CCR".
    - If the patient was not in a CR at transplant, but achieved a CR in your reporting period, you will mark "Complete Remission" and note the date the CR was achieved. You will then be prompted to answer the rest of the questions in this section. Refer to the 2402 instructions for the list of diagnostic testing for the disease you are reporting on.
  - NOTE: Once a patient has achieved a CR, the Best Response to HCT on subsequent 2450 forms will be CR, and that the date of best response was previously reported.
- Disease Relapse or Progression Post-HCT
  - The progress notes will mention if a patient had relapsed. However, this needs to be verified. To verify, check the following labs/tests for disease.
    - Chart Review
    - Labs/Path/Micro
    - Select the following boxes, if listed:
    - ACUTE MYELOID LEUKEMIA PANEL BY FISH?
    - CBC'S and MANUAL DIFFERENTIAL
      - Select all results from these lab tests within the appropriate timeline, and *click* "lab flowsheet".
    - PATHOLOGY REPORTS – Select each one listed
    - CHROMOSOME ANALYSIS – Select all tests with "Chromosome"
    - CHROMOSOME FISH-INTERPHASE
    - FLT3 ITD AND TKD MUTATION DETECTION
    - LEUK/LYMPH PHENOTYPING, FLOW CYTOMETRY
    - MYELOID MALIGNANCIES MUTATION PANEL NGS
    - MDS PANEL BY FISH
- Laboratory Studies
  - Check the pertinent lab results. If you have questions about reporting, consult another data manager.
- Disease Status
  - Compare the lab results with the CIBMTR MDS/MPN Response Criteria.
    - Make sure that the "date assessed" reflects the most recent testing pertinent to MDS/MPN before transplant.
- Common maintenance therapy in MDS/MPN patients is Jakafi.
  - This is not comprehensive, and the treatment should still be verified.

2116 – Plasma Cell Disorders (PCD) Post-Infusion Data

2116 Forms Instruction Manual

For all 21XX forms, use the same reporting period as the corresponding 2100 form

- Disease Assessment at Time of Best Response
    - IF the patient was in Complete Remission (CR) at transplant, this will always be reported as "CCR".
        - If the patient was not in a CR at transplant, but achieved a CR in your reporting period, you will mark "Complete Remission" and note the date the CR was achieved. You will then be prompted to answer the rest of the questions in this section, which requires you to look into the following diagnostic tests:
            - PATHOLOGY BONE MARROW
            - IMMUNOELECTROPHORESIS
            - BJPROTEIN QNT W/RFLX K/L FLC W RATIO
            - KAPPA/LAMBDA QUANT FLC, W RATIO SERUM
            - PET CT
    - NOTE: Once a patient has achieved a CR, the Best Response to HCT on subsequent 2116 forms will be CR, and that the date of best response was previously reported.
- Post- HCT Therapy
    - This is therapy that was given for maintenance, not for relapse, persistent or progressive disease. These drugs will usually be mentioned in the History of present illness, Interim History section and/or in the "Assessment" section of the provider notes.
    - To verify that the drug was given and what it was given for, you can either search each drug and verify that the dates in the MAR match, or you can:
        - Chart Review
        - SnapShot
        - Springboard Report: The springboard report will show the current treatment plan, but past treatment plans can be found if you scroll to the bottom of the screen.
            - Common maintenance drugs for Multiple Myeloma include daratumumab, velcade, revlimid, and dexamethasone.
                - This is not comprehensive, and the treatment should still be verified.
- Disease Status at time of Evaluation
    - The patient's disease status will be listed in the progress notes but it needs to be verified by looking at the following diagnostic testing:
        - PATHOLOGY BONE MARROW
        - IMMUNOELECTROPHORESIS
        - BJPROTEIN QNT W/RFLX K/L FLC W RATIO
        - PET CT
        - CHROMOSOME ANALYSIS

        - MULTIPLE MYELOMA PANEL BY FISH
        - KAPPA/LAMBDA QUANT FLC, W RATIO SERUM
        - LEUK/LYMPH PHENOTYPING, FLOW CYTOMETRY
    - Make sure that the "date assessed" reflects the most recent testing pertinent to plasma cell disorders within the reporting period.

2118 – Hodgkin and Non-Hodgkin Lymphoma (LYM) Post-Infusion Data

2118 Forms Instruction Manual

For all 21XX forms, use the same reporting period as the corresponding 2100 form

- Disease Assessment at Time of Best Response
    - IF the patient was in Complete Remission (CR) at transplant, this will always be reported as "CCR".
        - If the patient was not in a CR at transplant, but achieved a CR in your reporting period, you will mark "Complete Remission" and note the date the CR was achieved. You will then be prompted to answer the rest of the questions in this section, which requires you to look into the following diagnostic tests:
        - PET/CT
        - PATHOLOGY
    - NOTE: Once a patient has achieved a CR, the Best Response to HCT on subsequent 2116 forms will be CR, and that the date of best response was previously reported.
- Post-HCT Therapy
    - This is therapy that was given for maintenance, not for relapse, persistent or progressive disease. These drugs will usually be mentioned in the History of present illness, Interim History section and/or in the "Assessment" section of the provider notes.
    - To verify that the drug was given and what it was given for, you can either search each drug and verify that the dates in the MAR match, or you can:
        - Chart Review
        - SnapShot
        - Springboard Report: The springboard report will show the current treatment plan, but past treatment plans can be found if you scroll to the bottom of the screen.
- Relapse or Progression
    - The progress notes will mention if a patient had relapsed. However, this needs to be verified. To verify, check the following labs/tests for disease.
        - PET/CT
        - PATHOLOGY

Institutional Data Management

REDCap

- REDCap is an institutional database used to track patients who have consented to the LTFU of HSCT Biorepository.
- Patients data collection forms mirror CIBMTR time-points, pre transplant, 100-days, 6-months, 1-year, 2-year, annually. The RedCap database has minimal data compared to CIBMTR and the Data Managers will enter information into RedCap the same time CIBMTR data is entered.

Excel Files

- Multiple excel sheets are kept to house internal data that is frequently requested by physicians for outcome reporting.
- The UUPN (University of Utah Patient Number) sheet is the master list of all transplant patients since the inception of the BMT program in 1991. The UUPN sheet houses minimal data for every patient. This sheet is used to produce monthly transplant number reports, or any other basic information requested.

EMR/Data Warehouse Queries

- Physicians regularly request data not housed in our internal excel worksheets and requests to the data warehouse team for further information is sometimes required. The data warehouse pulls electronic data straight from EPIC. If information is needed, the data manager will e-mail contacts from the warehouse that can help with the requests.
- Justin Hadlock: Just.Hadlock@hsc.utah.edu
- Chad Freckleton: Chad.Freckleton@hsc.utah.edu

Outcome Data

FACT requires transplant related outcomes up to 1-year post transplant be reported in our Total Quality Meetings (TQM). The data managers will abstract these specific transplant related outcomes:

- Disease Status
- Performance status
- CMV reactivation
- Organ specific toxicities of immunosuppressive regimen:
    - CTCAE grade 3 tremors
    - Hypertension requiring new or increased doses of therapy
    - Renal insufficiency
    - PRES
- Acute and chronic GVHD and complications of their treatment:
    - Steroid induced diabetes
    - Steroid induced myopathy
    - Steroid induced hypertension requiring new or increased does of therapy

    - Osteoporosis
    - Cataracts
- Engraftment
    - You can refer to the Engraftment Reporting Structure Policy for more information.

Utah BMT Program at Huntsman Cancer Institute
Data Manager Competency Checklist

Staff Name _____ Date of Review _____

Reviewer _____ Date of Hire _____

Demonstrate Knowledge

Competency	Criteria	DK	Criteria Met	
Topic			Date	Initials
General				
1. Demonstrate knowledge of key members of BMT team.	Able to state role and function of attending physicians, APPs, nurse manager, CNC, nurses, MAs, transplant coordinators, CTRM staff			
2. Demonstrate involvement in department and continued growth in the knowledge of transplantation.	Attends relevant BMT meetings. Reads quarterly CIBMTR newsletter and CIBMTR manual updates. Completes continuing education when appropriate.			
Medical Records Management				
1. Demonstrate knowledge of the organization of the Epic EMR	Accurately/efficiently identify location of source documents			
2. Demonstrate skill at problem solving to obtain records.	All records required are available for audit. Thoroughly reviews and utilizes outside records from Care Everywhere or scanned into Media tab.			
3. Demonstrate extreme attention to detail.	Enter information accurately in a standardized format utilizing tools available in respective applications.			
4. Demonstrate ability to cite difficult source documentation.	Records where information that is difficult to find (i.e. long PDFs of outside records) is located so that it can easily be pulled and referenced for audit.			
5. Demonstrate knowledge of flow-sheet documentation.	State what information should be documented on flow sheets. Recognize missing information.			
6. Demonstrate knowledge of Cell Therapy and Regenerative Medicine (CTRM) Records	Obtains stem cell product documentation and works with CTRM staff to interpret source documentation required for stem cell product reporting			
Common Medical Terminology/Abbreviations				
1. Allogeneic	*Define the terms and state significance or use.*			
2. Autologous	*Define the terms and state significance or use.*			
3. Apheresis/Collection	*Define the terms and state significance or use.*			
4. Mobilization	*Define the terms and state significance or use.*			
5. Graft	*Define the terms and state significance or use.*			
6. Cryopreservation	*Define the terms and state significance or use.*			

Competency	Criteria	DK	Criteria Met	
Topic			**Date**	**Initials**
7. Harvest	*Define the terms and state significance or use.*			
8. Progenitor cells	*Define the terms and state significance or use.*			
9. Infectious Disease Markers (IDMs)	*Define the terms and state significance or use.*			
10. Engraftment	*Define the terms and state significance or use.*			
11. Co-morbidity	*Define the terms and state significance or use.*			
12. Aspergillus	*Define the terms and state significance or use.*			
13. Candida	*Define the terms and state significance or use.*			
14. CNS (central nervous system), IT (intrathecal), LP (lumbar puncture)	*Define the terms and state significance or use.*			
15. Induction therapy	*Define the terms and state significance or use.*			
16. Consolidation therapy	*Define the terms and state significance or use.*			
17. Mobilization therapy	*Define the terms and state significance or use.*			
18. Preparative/Conditioning Regimen	*Define the terms and state significance or use.*			
19. Myeloablative	*Define the terms and state significance or use.*			
20. Non-myeloablative	*Define the terms and state significance or use.*			
21. BCNU/Carmustine	*Define the terms and state significance or use.*			
22. Reduced intensity	*Define the terms and state significance or use.*			
23. Salvage therapy	*Define the terms and state significance or use.*			
24. sCR (stringent complete remission)	*Define the terms and state significance or use.*			
25. CR (complete response)	*Define the terms and state significance or use.*			
26. VGPR (very good partial remission)	*Define the terms and state significance or use.*			
27. HI (hematologic improvement)	*Define the terms and state significance or use.*			
28. PR (partial response)	*Define the terms and state significance or use.*			
29. PIF (primary induction failure)	*Define the terms and state significance or use.*			
30. SD (stable disease)	*Define the terms and state significance or use.*			
31. PD (progressive disease)	*Define the terms and state significance or use.*			
32. Relapse (recurrent disease)	*Define the terms and state significance or use.*			
33. DLI (Donor lymphocyte infusion)	*Define the terms and state significance or use.*			
34. Stem Cell Boost	*Define the terms and state significance or use.*			
35. CAR-T cells (chimeric antigen receptor T cells)	*Define the terms and state significance or use.*			
36. Extramedullary disease	*Define the terms and state significance or use.*			
37. Graft vs Host Disease (GVHD)	*Define the terms and state significance or use.*			
38. IP (interstitial pneumonitis)	*Define the terms and state significance or use.*			

Competency	Criteria	DK	Criteria Met	
Topic			**Date**	**Initials**
39. Kaplan-Meier analysis	*Define the terms and state significance or use.*			
40. G-CSF (granulocyte colony stimulating factor)	*Define the terms and state significance or use.*			
41. HLA (Human Leukocyte Antigen) Typing	*Define the terms and state significance or use.*			
42. HPC-A (Hematopoietic Progenitor Cell – Apheresis)	*Define the terms and state significance or use.*			
43. HPC-M (Hematopoietic Progenitor Cell – Marrow)	*Define the terms and state significance or use.*			
44. DFS (disease-free survival)	*Define the terms and state significance or use.*			
45. OS (overall survival)	*Define the terms and state significance or use.*			
46. RR (relapse rate)	*Define the terms and state significance or use.*			
47. TRM (treatment-related mortality)	*Define the terms and state significance or use.*			
48. PCR (Polymerase Chain Reaction)	*Define the terms and state significance or use.*			
49. NGS (Next Generation Sequencing)	*Define the terms and state significance or use.*			
50. SAE (serious adverse event)	*Define the terms and state significance or use.*			
51. VOD (veno-occlusive disease)	*Define the terms and state significance or use.*			
Data Management Functions				
1. Calculate time to engraftment of neutrophils.	Accurately calculate time to ANC to 500, 1000, etc.			
2. Calculate time to engraftment of platelet count.	Accurately calculate time to platelet engraftment to 20k, 50k. Account for platelet transfusions.			
3. Calculate absolute cell counts from CBC reports expressed in percentages.	Accurately convert CBC reports expressed in percentages to absolute values.			
4. Abstract clinical information from bone marrow biopsy reports.	Able to identify normal and abnormal reports. Able to interpret results in context of CIBMTR response criteria.			
5. Abstract clinical information from cytogenetic reports.	Able to identify normal karyotype vs abnormal reports. Accurately report cytogenetic results for CIBMTR.			
6. Maintain/document consent forms.	Able to state documentation/ALCOA requirements.			
7. Karnofsky performance scale	Able to state documentation requirements. Passes audit.			
8. Produces trended BMT outcome data per FACT requirements.	Prepares quarterly report. Passes audit.			
Data Submission				
1. Complete CIBMTR CRID assignment forms.	Abstract data (97% accuracy less than < 3% major errors).			
2. Complete CIBMTR TED forms.	Abstract data (97% accuracy less than < 3% major errors).			
3. Complete CIBMTR CRF/disease-specific inserts.	Abstract data (97% accuracy less than < 3% major errors).			
4. Complete CIBMTR Product forms.	Abstract data (97% accuracy less than < 3% major errors).			
5. Complete CIBMTR Cellular Therapy forms.	Abstract data (97% accuracy less than < 3% major errors).			
6. Identify and respond to CIBMTR queries	Abstract data (97% accuracy less than < 3% major errors).			

Competency	Criteria	DK	Criteria Met	
Topic			**Date**	**Initials**
7. Meet CIBMTR CPI Period Requirements	Completes a minimum of 90% forms assigned per reporting period.			
BMT Data Monitoring				
1. Retrieve baseline information.	Abstract data (Less than 3% critical field errors).			
2. Abstract and enter diagnosis-specific patient data.	Abstract data (Less than 3% critical field errors).			
3. Abstract and enter pre-transplant patient data.	Abstract data (Less than 3% critical field errors).			
4. Abstract and enter PBSC collection data.	Abstract data (Less than 3% critical field errors).			
5. Abstract and enter Auto infusion data.	Abstract data (Less than 3% critical field errors).			
6. Abstract and enter Allo infusion data.	Abstract data (Less than 3% critical field errors).			
7. Abstract and enter cell therapy infusion data.	Abstract data (Less than 3% critical field errors).			
8. Abstract and enter Patient and/or Donor characteristics	Abstract data (Less than 3% critical field errors).			
9. Abstract and enter conditioning therapy data	Abstract data (Less than 3% critical field errors).			
10. Abstract and enter follow-up data.	Abstract data (Less than 3% critical field errors).			
11. Abstract and enter acute GVHD data.	Abstract data (Less than 3% critical field errors).			
12. Abstract and enter chronic GVHD data.	Abstract data (Less than 3% critical field errors).			
13. Abstract and enter “Events.”	Abstract data (Less than 3% critical field errors).			
14. Abstract and enter SAE’s.	Abstract data (Less than 3% critical field errors).			
15. Track patient survival/outcomes according to Total Quality Management Plan SOP criteria.	Prepare list of patients due for follow-up based upon SOP 002. Review outcomes with medical director. Accurately update follow-up information in database.			
Database Analysis and Management				
1. Export Data for Analysis.	Selects defined data, export data to excel spreadsheets, sorts based upon established criteria as needed by physicians.			
2. Enter patient data into BMT internal REDCap database	Enters patient data into internal REDCap database when completing relevant patient’s CIBMTR forms.			
3. Prepare and submit annual ASBMT RFI for payer submission.	Work with Program Quality Manager to complete RFIs as needed			
Management of Regulatory Documentation				
1. Prepare annual reports and regulatory documents for clinical staff and IRB review	Submits and maintains IRB renewal documents for CIBMTR database and NMDP repository			
2. Assist with FACT documentation as needed	Coordinates with Program Quality Manager to track required outcomes and other relevant program data			
3. Maintain patient consent forms for CIBMTR Database and NMDP Repository.	Updates the team when consent forms are renewed. Informs of any changes to consents, etc.			
Other:				

Competency	Criteria	DK	Criteria Met	
Topic			**Date**	**Initials**
1. Attend all departmental and hospital meetings as applicable.	i.e. BMT SOP/CPG, TQM, and Research Operations Meeting			
2. Continuing education	Obtain yearly CE credits as required by FACT standards. Can be earned by attending research meetings, University RATS courses, or CIBMTR Clinical Research Professionals and Data Management meeting at annual TCT meetings.			

Comments

Staff Name	Initials	Date	Reviewer	Initials	Date
_____	_____	_____	_____	_____	_____