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Change highlights

- Investigating how to collect donor IDs once on the pre-TED and auto-populate across the 2004/2005/2006 to eliminate duplicate reporting and reduce data quality issues.
- Product processing/manipulation moved from F2400 to F2006. This will allow manipulations to be linked to a specific product. Currently, if there two products from two donors, all manipulations are reported together in one section. We are unable to link manipulations to different products.
- Moved donor questions (blood type, Rh factor) from F2006 to F2400.
- Implemented “check all that apply” formatting when applicable.

F2400 change summary

Key Fields

Removed Hospital and Unit fields:

- Confirmed they are not used in studies.

Event date moved from Q11 to the key fields:

- This is consistent with event date being in the key fields of other forms. Field is currently auto-populated from the F2814 Indication form and will be auto-populated in the key fields.

Recipient Information

Title updated from “Recipient Data” to “Recipient Information:”

- Standardizes section titles between Recipient and Donor so section titles now match.

Ethnicity and Race will be moved to the F2804 CRID Assignment Form and will be auto-populated onto the F2400:

- The field cannot be removed from the form since RDB does not get F2804 data. We will collect ethnicity and race at the time of recipient registration to eliminate duplicative reporting on multiple forms.
- Changed Race to a ‘check all that apply’ list, instead of a multiple. There will be validation in FN3 that will give an error if “unknown” is selected with any other option.
- Race detail list will filter based on option reported for Race:
 - Example: if ‘white’ is reported for race, race detail will only show race details associated with ‘white.’
- Added race detail option for ‘other black.’

Country of primary residence added to this section (moved from the 2000):

- Country list expanded to be the same option group as country of birth from F2804 (ISO country options).
- State of residence added for residents of Brazil.
- Province/territory of Residence added for residents of Canada.

Adding a field for NMDP RID, which will be auto-populated from F2804 CRID Assignment Form:

- The NMDP RID is currently captured on the F2804, but is frequently missing for 2nd transplants, where the data manager must go back and update the F2804. By showing the field on the pre-TED, it will serve as a data quality check. The field must still be updated on the F2804, which remains the ‘source of truth.’
- The last four digits can be optional. FN3 already allows for submission of 9 digits, but the manual will include additional instruction.

Recipient blood type and Rh factor have been moved from the F2000 Baseline to the F2400 pre-TED

- Review committee felt this is widely known information and should be collected on every patient.

Recipient consent questions have been moved and consolidated to the Recipient Data section

- Updated question text to include “IRB / ethics committee (or similar body).”
 - More inclusive for international centers.
- The question “permission to be directly contacted for future research” has been updated to include “contacted by CIBMTR for...” and has been made a child question of the research database consent question. A recipient cannot consent to future contact without also consenting to the research database. There will be just one date field collected instead of two separate ones.
 - Contact details will be collected on the new IRB approved consent form.
- The question regarding research sample submission has been moved from the F2006 and made a child of the research sample repository consent question. This will eliminate data quality errors having these questions split across two forms.

Adding PIDTC to the study sponsor option list:

- To facilitate randomization to CRF track for the PIDTC study.

Hematopoietic Cellular Transplant (HCT) and Cellular Therapy

Moved HCT date to the key fields section, renamed it “Event Date:”

- This is consistent with event date being in the key fields of other forms.

Moved question regarding planned subsequent HCT to a parent question:

- Still answered for autos only, now first question in section.

Updated question text from “Was this the first HCT for this recipient” to “Has the recipient ever had a prior HCT?”

- Internal reviewers felt this wording makes the question clearer. It will change the meaning of the answer: a prior ‘no’ will now be a ‘yes.’ Internal groups that map the data are aware of this change.

The option list for “reason for current HCT” was harmonized with the F2450 ‘indication for current HCT:’

- the option “planned second HCT, per protocol” has been updated to “Planned subsequent HCT, per protocol.”
 - Covers scenarios where form is being completed for 3rd+ HCT.

Added questions to capture prior cellular therapies:

- These questions include: date of prior CT, institution, and source of the prior CT.

Donor Information

Changed how we collect the donor type:

- Specify donor has been simplified to “auto, alloR, and alloU.”
- Product has been moved higher up on form, updated to ‘check all that apply.’
- Added genetically modified (yes/no) question.
- Moved question to specify related relationship higher up on form:

- o Consolidated relationship questions from F2006 and F2005.
 - o Added 'grandparent' and 'grandchild' as options.
- Added back degree of mismatch of related donor type:
 - o At the request of the Biostats group used for high-level comparison.
- Added question to capture unrelated donor type (HLA match/mismatch).
- Added question asking if "NMDP facilitated the product."
- The combination of these questions will enable calculation of the donor type as listed on R5 (Auto, Auto CBU, NMDP, NMDP CBU, etc.) and will allow capture of NMDP Related HCTs. This format will simplify data entry of the form.
- Donor and product type, and related donor type will be mandatory fields, no override allowed.

Added field to capture new GRID (Global Registration Identifier for Donors):

- Field will be optional for now as GRID use is phased in.

Added option for "unknown" for the question "Is the CBU ID also the ISBT DIN:"

- Donor blood type and Rh factor fields moved from the F2006 and consolidated into the Donor Information section.

Added "indeterminant" as an option for Donor CMV.

Donor consent questions moved and consolidated into the Donor Information section:

- Updated question text to include "IRB / ethics committee (or similar body)."
 - o More inclusive for international centers.
- The question regarding research sample submission has been moved from the F2006 and made a child of the research sample repository consent question. This will eliminate data quality errors having these questions split across two forms.

Auto HCT mobilization questions:

- Removed questions ask for number of mobilizations.
- Updated question about mobilization agents to "What agents were used to mobilize the autologous recipient for this HCT?" Options "G-CSF," "Plerixafor (Mozobil)," "Combined with chemotherapy" are needed for a corporate report.
- Harmonized with the similar section on the F2006 and included option for "Anti-CD20." This will not be asked on F2006.

Removed question "was plerixafor give prior to prep reg?"

Product processing/manipulation

These questions have been updated and consolidated on the F2006:

- Questions were moved from being in a separate section on the pre-TED to being on the product form. This will allow manipulations to be linked to a specific product. Currently, if there two products from two donors, all manipulations are reported together in one section. We are unable to link manipulations to different products. Confirmed with the stats group that TED level manipulation data is not used in studies.

Clinical Status of Recipient Prior to the Preparative Regimen (Conditioning)

Added “indeterminant” as an option for Recipient CMV.

Added option choice of ‘indeterminant’ for recipient CMV-antibodies question:

- “Report the cytomegalovirus (CMV) status of the recipient immediately prior to the start of the preparative regimen. For the purposes of this manual, the term “immediately prior” represents the **pre-HCT work-up phase**, or **approximately one month** prior to the start of the preparative regimen. An exception to this definition would apply to a recipient with a documented history of a “reactive” CMV test result. In this case, the CMV test may not be repeated during the pre-HCT work-up phase. Therefore a timeframe of greater than one month prior to the start of the preparative regimen is acceptable.”

Comorbid Conditions

Updated question text to remove "proven" now asks "is there a history of invasive fungal infection?"

Added questions to capture glomerular filtration rate and complex congenital heart disease for recipients under 18 yrs:

- Based on recommendations from pediatric risk adjustment group.

Updated the co-morbidity parent question text to reference the HCT-CI specifically.

Changed the comorbidities list to a ‘check all that apply’ list:

- Review committee agreed that the “no” or “unknown” answers did not matter for scoring.
- Clarified instructional text on the options.
- Combined solid tumor and heme malignancy into 'prior malignancy,' removed year of diagnosis after it confirmed the data were never used.

Added new question to capture dialysis at transplant:

- Answered only for renal comorbidity.

New question asking for prior malignancy as a ‘check all that apply’ list:

- Includes prior solid tumors and prior heme malignancies other than the primary disease for which the HCT is being done.
- Confirmed that the ‘year of diagnosis’ has never been used in studies.

Added new augmented HCT-CI criteria:

- Added as separate questions to keep the original HCT-CI criteria intact. These criteria are not yet validated: serum albumin lab value and collection date, platelets, platelet lab value, and if platelet transfusion occurred less than 7 days before date of test.

Added questions to capture prior solid organ transplant and year of transplant:

- Will support queries received through Info Request

Pre-HCT Preparative Regimen (Conditioning)

Added a decimal place to the value for actual weight as initiation of pre-HCT prep reg.

Removed 'date pre-HCT preparative regimen began':

- Form instruction says to use the earliest date from the radiation start date or chemotherapy start date. This field is a duplication, confirmed with the stats group it can be removed.

Removed prescribed dose per fraction and number of days when radiation is fractionated:

- This was previously used as a validation of what was reported.

Simplified prep reg drug list to a multiple:

- Each drug given will be submitted as a new instance.
- Reviewed drug list and removed options no longer used, added new options.
- Added question to specify administration of Busulfan (oral, IV, or both).

Additional drugs given in the peri-transplant period

Created a new section for drugs that can be given as both part of prep reg or GVHD prophylaxis:

- The instruction manual explains where to report the drug based on the date it was given. By creating a new section and just capturing the date given, CIBMTR can determine if it was prep or prophylaxis.
- Added Defibrotide, KGF, and Ursodiol as options.

GVHD Prophylaxis

Updated question text from "was GVHD prophylaxis planned/given" to just "planned:"

- Will solve data issues with the pre-TED and 2100 matching for prophylaxis.

Updated GVHD prophylaxis drug list and made it a 'check all that apply.'

Removed question about KGF:

- This question was study specific, and study enrollment is complete.

Post-HCT Disease Therapy Planned as of Day 0

Removed duplicate question about subsequent HCT planned:

- Now captured in above section since question was moved to be a level 1.

Updated post-HCT therapy list options and made it a 'check all that apply' list.

F2402 change summary

Primary Disease of HCT / Cellular Therapy

Added new option for "Tolerance induction associated with solid organ transplant" and "Recessive Dystrophic Epidermolysis Bullosa"

- These two options were listed in the other specify field often enough to warrant inclusion.

AML

Added place holder questions to capture string field for cytogenetic results.

Acute Lymphoblastic Leukemia (ALL)

Options “B-lymphoblastic leukemia/lymphoma, with iAMP21” and “Early T-cell precursor lymphoblastic leukemia” have had “(provisional entity)” removed per the 2017 WHO classification.

Check box for “T-cell lymphoblastic leukemia / lymphoma” added back to the form after discovery it had been deleted.

Hypodiploid changed from (<45) to (<46) in abnormalities list.

Added place holder questions to capture string field for cytogenetic results.

Chronic Myelogenous Leukemia (CML)

Complete hematologic response has been split into two.

Myelodysplastic (MDS) / Myeloproliferative (MPN) Diseases

Cytogenetic abnormality lists have been updated to ‘check all that apply.’

Added place holder questions to capture string field for cytogenetic results.

Specify the cell line examined to determine HI status updated to ‘check all that apply.’

Multiple Myeloma / Plasma Cell Disorder (PCD)

Cytogenetic abnormality lists have been updated to ‘check all that apply.’

Added place holder questions to capture string field for cytogenetic results.

Solid Tumor

Classification list has been alphabetized.

Inherited abnormalities of erythrocyte differentiation or function

Questions have been added for beta thalassemia major and sickle cell/sickle thalassemia:

- These questions were developed by a Beta thalassemia revision committee. Additionally, chimerism data will be collected via F2450 for recipients on the TED track.
- Additional questions added by pediatric risk adjustment group.

Disorders of the Immune System

Questions added by pediatric risk adjustment group.

Inherited Disorders of Metabolism

Question added by pediatric risk adjustment group for ALD to capture Loes composite score.

Histiocytic Disorder

Questions added by pediatric risk adjustment group for HLH.

Autoimmune Diseases

Remove the following 'other disease subtype, specify' questions: Specify other arthritis, Specify other juvenile idiopathic arthritis, Specify other connective tissue disease, Specify other vasculitis, Specify other autoimmune neurological disorder.

Tolerance induction associated with solid organ transplant

Questions added to capture when an HCT is given as tolerance when associated with a solid organ transplant.

F2006 change summary

Key fields

Donor Identification moved into key fields:

- It has been proposed to move all donor identification to the key fields on the F2004/2005/2006. These donor ID fields will be auto-populated from source data on F2400 pre-TED, which will eliminate data entry errors of incorrect donor IDs across the forms.
- Removed Donor Identification section.

Pre-Collection Therapy

Updated question text from “did the donor receive therapy” to “did the donor receive growth and mobilizing factors:”

- To be asked for allogeneic donors only.
- Removed options for systemic therapy (chemo) and other therapy. Chemo option will be captured on 2400.
- Option list updated to a ‘check all that apply’ list.
- Harmonized with pre-TED mobilization question.

Product Collection

Removed questions asking for number of collections.

Anticoagulant question text updated from “were anticoagulants added to the product *during collection*” to “were anticoagulants or other agents added to product *between collection and infusion*.”

- List of anticoagulants changed to a ‘check all that apply’ list.

Removed question “were anticoagulants added to the product before freezing.”

Product Transport and Receipt

Updated option values to specify the shipping environment to include room temperature, cooled, and frozen.

Questions about shipping environment no longer asked for CBU only.

Total nucleated cells and CD34+ cells collected in this section will count as the “Product arrival” analysis time point.

Product Processing and Manipulation

Removed question for NMDP products “was fresh product received?”

- Confirmed with NMDP, this is not needed or used in any reports. If an NMDP product needs to be cryopreserved, that will be tracked by NMDP.

Replaced the question “was a compartment of the bag thawed” with “specify the percent of the product that was thawed:”

- Options are 80%, 20%, other percent

Removed question asking if there were multiple bags.

Updated question text from “time *product ready for infusion/expansion*” to “time of *thaw completion*:”

- Review committee decided this wording better reflects the intent of the question.

Removed question asking if the primary container was intact.

Update question text to remove ‘adverse events’ from “did any incidents or product complaints occur while preparing or thawing product:”

- This does not change the intent of the question.

Product processing and manipulation questions updated and consolidated on the F2006:

- Duplicate questions removed from the pre-TED.
- Created two parent questions to distinguish between processing and manipulation.
- Lists are now ‘check all that apply.’

Autologous Products Only

Removed entire section.

Product Analysis

Removed “pre-cryopreservation” and “post-thaw” time points:

- Question to ask the total number of cells prior to cryopreservation in product transport/receipt section counts as “product arrival,” answered for CBU only.

Viability will be collected per cell type instead of overall viability:

- Added for TNC, CD34, CD3, CD4, CD8.

Added field to capture “total CFU-GEMM.”

Question text updated from “were cultures performed before infusion to test the product(s) for bacterial or fungal infection?” to “were any *positive* cultures (for bacterial or fungal infections) obtained from the product at the transplant center?”

- Added option for “pending” to question asking for testing culture. Need a way to submit the form to complete when culture results are not completed at the time of filling out the form. CIBMTR DQT will create a query to monitor this field.

Questions for cultures performed on the product have been changed to a multiple choice question:

- Each culture result will have its own instance of result and organism code.

Product Infusion

Remove question asking “was more than one product infused.”

Remove question asking “was the product infusion described on this insert intended to produce hematopoietic engraftment?”

- This question exists on the pre-TED to distinguish between HCT products and co-infusions.

Remove question “date infusion started:”

- Duplicate of event date.

Question text updated from “Was the entire volume of product infused?” to “was the entire volume of *received* product infused?”

Removed total volume of product plus additives intended for infusion:

- Duplicate of date reported in the at infusion time point of product analysis.

Updated option group of route of product infusion to remove “intraperitoneal.”

Donor/Infant Demographic Information

Donor blood type and Rh factor moved to pre-TED.

Removed question asking site of central line placement.

Updated question asking for biological relationship of the donor to the recipient to remove ‘unrelated.’ Question will only apply to related donors.

Race and race detail updated to ‘check all that apply.’

- Added race detail option for ‘other black.’

Removed question regarding biological relationship of donor to the recipient:

- This was asked on three different forms, consolidated to the pre-TED.

Updated option list for potentially transplantable genetic diseases to ‘check all that apply.’

Added question to capture “was the donor/product tested for other transferable genetic or clonal abnormalities?”

- Options include CHIP, monoclonal B-cell lymphocytosis, other.

Added question to capture if recipient gave auto transfusion units.

Reformatted question asking if donor received blood transfusion.

Sample repository questions moved to the pre-TED.

F2004 change summary

Key fields

Donor Identification moved into key fields:

- It has been proposed to move all donor identification to the key fields on the F2004/2005/2006. These donor ID fields will be auto-populated from source data on F2400 pre-TED, which will eliminate data entry errors of incorrect donor IDs across the forms.
- Removed Donor Identification section.
- Updated CRID to 'CIBMTR Research ID' in key fields.

New question to capture NAT testing for HBV.

Split question for NAT test for HIV-1 and HCV into separate questions.

Removed question about Anti-HTLV I/II, syphilis, CMV, WNV, Toxoplasmosis.

Infectious Disease Marker

Updated infectious disease list to remove Human T-Lymphotropic Virus question, Syphilis, CMV, West Nile Virus, and Toxoplasmosis.

F2005 change summary

Key fields

Donor Identification moved into key fields:

- It has been proposed to move all donor identification to the key fields on the F2004/2005/2006. These donor ID fields will be auto-populated from source data on F2400 pre-TED, which will eliminate data entry errors of incorrect donor IDs across the forms.
- Removed Donor Identification section.

Donor/Cord Blood Unit Identification

This form will collect HLA data only on recipient and final donor(s):

- No longer collect F2005 for non-donors (e.g., father/uncle/aunt who was not the donor).

Remove list of biological relationship:

- Information is consolidated to pre-TED.

Remove character limit on the field? For this form and 2402 cytogenetic field, 2005 already allows for copy/paste answers.

F2450 change summary

Subsequent Transplant

Updated "what was the indication for subsequent HCT" options to match with the pre-TED.

Added additional qualifiers to question "Has the recipient received a cellular therapy since the date of last report? (e.g., CAR-T, DCI)."

Graft vs. Host Disease

Added questions to capture organ staging since the date of the last report:

- Determined not to add reporting burden since each organ stage must be determined to calculate overall maximum grade. This will allow flexibility of the GVHD criteria used.

Updated option for grade II of acute GVHD to include “persistent nausea or vomiting.”

Liver Toxicity Prophylaxis

Updated therapy list to ‘check all that apply.’

Chimerism Studies

This section will be enabled for beta thalassemia and sickle cell disease recipients as well as CBUs.

Updated instructional text.

Added field to capture new GRID (Global Registration Identifier for Donors):

- Field will be optional for now as GRID use is phased in.

Post-HCT Therapy

Updated therapy list to ‘check all that apply.’

Relapse or Progression Post-HCT

Updated question text from “Was the date of clinical/hematologic relapse or progression previously reported?” to “Was the date of the first clinical/hematologic relapse or progression previously reported?”

- The intent of the 2450 has always been to capture the first relapse only. This was lost in the last revision.

Updated question text to remove “decreased/loss of chimerism” from “Was intervention given for relapsed, persistent or progressive disease since the date of last report?”

- Removed ‘decreased/loss of chimerism’ from “specify the reason intervention was given.”
- Updated method of detection to ‘check all that apply.’
- Updated therapy list to ‘check all that apply’ and alphabetized drug names.