CIBMTR MANUAL
Supplemental Form: R02-09
(Sup-R02-09)
General Instructions

Questions regarding this supplemental Form should be directed to the Study CRCs:
Milwaukee campus: Swati Kulkarni (skulkarni@mcw.edu)
Minneapolis campus: Sue Logan (slogan@nmdp.org)

READ BEFORE YOU BEGIN:

This is a supplement to Report Forms previously submitted to CIBMTR (formerly IBMTR/ABMTR in Milwaukee) and NMDP which are referred to as 'legacy data'. Some of the questions on this Supplemental Form were also asked on those previously submitted Report Forms. Supplemental Form questions are indicated in this manual by a *distinctive font*.

The AML/ALL Supplement (2520) contains 281 questions:

- If a CIBMTR legacy Report Form was submitted with complete and accurate data, you may be able to skip 204 questions and only fill a maximum of 77 supplemental questions.
- If an NMDP legacy Report Form was submitted with complete and accurate data, you may only need to fill a maximum of 77 + 131 questions (not asked on the NMDP Forms).
- The remaining questions are either missing from the legacy Report Form or to make corrections to CIBMTR data.
- NMDP data corrections must be made using the appropriate retired Error Correction Form.
- A number of the required questions may be skipped if a "parent" question is answered "no" (e.g., Q37 LK or Q20 MDS) genetic testing using the FISH method (Fluorescent In-situ Hybridization) was not done at diagnosis eliminates 31 questions.

This manual follows the order of questions in the supplemental form. If completing a supplement for AML/ALL follow the questions labeled LK; for MDS follow the questions labeled MDS, e.g. Q1 LK / Q1 MDS refers to supplemental Question 1. The next question, Q2 MDS, refers to an extra question that was on the MDS form and not on AML/ALL.

Legacy Form question numbers are shown in brackets after the question text, e.g. Date of relapse {AML Q130, ALLQ110 130 Q99} refers to CIBMTR 095-AML Q130, CIBMTR 095-ALL Q110, or NMDP Form 130, 530, 630 Q99 Report Forms. These question numbers are also referenced in this manual, so a single manual may be used for AML, ALL, and MDS. If you are missing copies of those Forms, contact the Study CRC as directed above. (Note: Forms submitted via StemSoft software should be available from the software at your center.)

ERROR CORRECTIONS:
To ensure accuracy of data and consistency across Forms, please compare the medical record to the legacy data. If an answer on a previously submitted Form does not match with the recipient medical records, please take the following action:

If the Forms were sent to CIBMTR (Milwaukee):
Mark the corrected data in the appropriate question on the R02-09 Supplemental Form. Legacy Report Forms for CIBMTR did not have a formal mechanism to report corrections to submitted data. This supplemental Form serves

the purpose for making corrections to data included in this study. Also note that prior to the advent of a DCI Report Form, the legacy transplant Report Forms were used to collect data on DCIs with the understanding that the procedure was NOT a transplant, and would NOT be analyzed as such. When reading questions that use the terminology "conditioning" or "transplant" but the infusion was a DCI, substitute the phrase "just prior to infusion" for "conditioning" and substitute "DCI" for "transplant."

If the Forms were sent to NMDP (Minneapolis):
Contact your center liaison or the Study CRC for an Error Correction Form (E.C.). Complete the E.C. Form that corresponds to the incorrect legacy data and submit it with the supplemental Form. Mail, fax, or E-mail the completed Error Correction Form to your current CIBMTR campus.

If you do not need to make corrections to the legacy data, skip to the supplemental data questions identified by a *special font.*

Some older versions of the NMDP forms did not collect some of the data that is marked on this supplemental form as previously submitted; in this case, *please provide the data at this time in the indicated questions*.

If you have any special circumstances that are not addressed by these instructions, please contact the study CRC or your center liaison.

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Abbreviations:

CBC – Complete Blood Cell Count
CRC – Clinical Research Coordinator (a.k.a. the Study CRCs or your CIBMTR liaison)
DCI – Donor Cellular Infusion (various cell sub-types)
DLI – Donor Lymphocyte (or Leukocyte) Infusion (usually T cells)
E.C. – NMDP Error Correction Form
FISH – Fluorescent in situ Hybridization
GVHD – Graft-versus-Host-Disease
HSCT – Hematopoietic Stem Cell Transplant
PBSC – Peripheral Blood Stem Cell
PCR – Polymerase Chain Reaction
Sup – This Supplemental Report Form
WBC – White Blood Cell

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CIBMTR Center #:					

Enter the five-digit CIBMTR Center Number (CCN). The CCN replaced the three-digit CIBMTR Team number and three-digit NMDP TC code in December 2007 for data submission in the FormsNet2 system.

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CRID:										

The CIBMTR Recipient Identification (CRID) number is a lifelong ID assigned by CIBMTR to each recipient. It is generated by submitting the CRID Form (2804) prior to the recipient's first HSCT. Recipients in the CIBMTR or NMDP databases as of December 2, 2007, have been assigned a CRID number by CIBMTR.

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DATA ELEMENT: Recipient NMDP ID: [ ][ ][ ] – [ ][ ][ ] – [ ]

DIRECTIVE(S): The Recipient IDentification (RID) number is assigned by NMDP. If you do not know the recipient's ID number, please contact the Study CRCs. If the HSCT was not facilitated by NMDP, leave this field blank.

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DATA ELEMENT: NMDP TC Code: [ ][ ][ ][ ]

DIRECTIVE(S): The Transplant Center (TC) Code is assigned by NMDP. If you do not know your Center's TC code, please contact the Study CRCs. If the HSCT was not facilitated by NMDP, leave this field blank.

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DATA ELEMENT:

Recipient Local ID (NMDP only): [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

DIRECTIVE(S): This ID number is assigned by your Center for your own tracking purposes; you may leave this field blank. If the HSCT was not facilitated by NMDP, leave this field blank.

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DATA ELEMENT: CIBMTR Team: [ ][ ][ ][ ]

DIRECTIVE(S): The Team Number is assigned by CIBMTR. If you do not know your Center's Team number, please contact the Study CRCs.

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DATA ELEMENT: CIBMTR IUBMID: [ ][ ][ ][ ][ ][ ]

Institutional unique blood or marrow transplant ID number

DIRECTIVE(S): The IUBMID Number is assigned by your Center to uniquely identify your recipient and must be HIPAA compliant. For more information regarding assigning IUBMID numbers, please refer to p26: http://www.cibmtr.org/DataManagement/TrainingReference/Manuals/Retired/Documents/CIBMTR_Reg_Manual_Re.pdf
OR
http://www.cibmtr.org/DataManagement/TrainingReference/Manuals/DataManagement/Documents/section7.pdf

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DATA ELEMENT: Today's Date: [ ][ ] Month [ ][ ] Day [2][0][ ][ ] Year

DIRECTIVE(S): The date this document is complete and checked for accuracy. CIBMTR: formerly known as Date of Report.

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DATA ELEMENT:

Date of HSCT for which this form is being completed:

Month Day Year

DIRECTIVE(S): Date of HSCT should reflect the date of HSCT #1 (a.k.a. transplant #1).

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DATA ELEMENT:

CIBMTR Use Only

Sequence Number:

DIRECTIVE(S): Leave these fields blank.

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DATA ELEMENT: Date Received:

DIRECTIVE(S): The date that Sup-R02-09 arrives at CIBMTR (your assigned campus). Leave this field blank.

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DATA ELEMENT: Form ID Number: _ _ _ _ – _ _ _ _ _ _

DIRECTIVE(S): The Form ID is assigned by CIBMTR for Form tracking purposes. Leave this field blank unless you are certain what Form ID was assigned to your recipient by CIBMTR. If the HSCT was facilitated by NMDP, leave this field blank.

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Timeline Information for the Study Data

All questions in the Post-Hematopoietic Stem Cell Transplant (HSCT) section refer to the first relapse after the recipient's ***first*** HSCT. The data was possibly submitted on a legacy Report Form from CIBMTR or NMDP, rather than in the FormsNet2 system. If that is the case, in the legacy system CIBMTR (prior to December 3, 2007) requested that a subsequent HSCT Form or DCI Report Form be completed when a DCI (e.g. DLI) was performed. This supplement integrates the Form questions from the legacy system in order to link potentially existing data to the supplemental data needed at this time. If the legacy data was never submitted, it is now required for this study.

The R02-09 Supplemental Form contains two "Post" evaluations. The first is from Post-HSCT #1 at the time the post-HSCT relapse occurred. The second "Post" evaluation at the end of the Supplemental Form is from the period of time after the DCI/DLI. The way DCI data is collected in FormsNet2 is different. If you have any questions about completing this study request, please do not hesitate to ask.

The following link to the legacy CIBMTR Core Insert provides instructions regarding what Forms were to be completed when a DCI/DLI was given to a recipient post-HSCT. Go to Core Insert p16, Q318 to view timeline diagrams. This may orient you as to which Forms may have been completed for the recipient.

http://www.cibmtr.org/DataManagement/DataCollectionForms/Pages/DataCollectionFormInfo.aspx?dcfid=154

DIRECTIVE(S): Recipient medical record should match any previously submitted data from 095-AML, 095-ALL, 095-AMLFU, 095-ALLFU, NMDP Form 130, 530, 630, NMDP Form 140, NMDP Form 150 for HSCT #1.

Sup-R02-09 Questions	095-AML question #s	095-AMLFU question #s	095-ALL question #s	095-MDS question #s	NMDP 130 question #s	NMDP 140 question #s
	These data are after the HSCT #1 at the time of relapse, but before the DCI/DLI:					
Date of 1st post-HSCT#1 **Relapse**	130	12	110	107	99	94
Bone Marrow	131	13	111	-	100a	95a
CNS	132	14	112	-	100b	95b
Testes	133	15	113	-	100c	95c
Other	134	16	114	-	100d	95d
Therapy	135	17	115	109	101	96
Chemo	138	20	118	109	102b	97b
DLI*	141	23	121	109	102e	97e
Growth Factors	143	25	123	109	102g	97g
Immunotoxin	140	22	120	109	102d	97d
Interferon α	137	19	117	109	102a	97a
Interferon β	136	18	116	109	-	-
Second HSCT*	142	24	122	109	102f	97f
Withdrawal of Immune Suppression	139	21	119	109	102c	97c
Other	144	26	124	109	102h	97h
Cr achieved?*	145	27	125	-	-	-
	These data are after the DCI/DLI:					
Current status post DCI #1	129	11	129	106	98	93

- *Although DCI/DLI and subsequent HSCT are listed in the options for treatment of the post-HSCT relapse, there was an important reporting caveat at the time those Forms were in effect. The caveat was to cut off the data for the Report Form for either of those specific treatments, at one day prior to a preparative regimen (if given) or one day prior to the infusion (if no prep. regimen used). So, the response from a DCI or subsequent HSCT would NOT be reflected on the Report Form in which it was first reported. The Forms were to 'start over' and it was on that new set of Forms that the response to DCI or subsequent HSCT would be captured.

Pre-HSCT #1 Information

Note: R02-09 LK Q1-91 and R02-09 MDS Q1-55

The time frame listed for these questions is pre-HSCT #1, "at diagnosis" or "preconditioning", and are accurate. Study R02-09 will compare abnormalities present prior to the first HSCT with those present at first relapse post-HSCT. These questions are the only ones referring to pre-HSCT data. When answering these questions take care to note the time frame of the documents in the recipient's medical record.

Q1 LK/Q1 MDS: Were cytogenetics tested at diagnosis, before the start of treatment? {AML Q28} {ALL Q10} {MDS Q26} {120-Insert I, Q18} {120-Insert II, Q9} {120-Insert V, Q26}

DEFINITION: Cytogenetic tests look at chromosomes in the cells, typically about 20 cells, for abnormalities. FISH (Fluorescent in situ Hybridization) is a method of looking for the same abnormality in typically 200-500 cells, but via a fluorescent tag on the corresponding gene.

FISH was reported in the cytogenetic section of the legacy Forms, not molecular, as the level of sensitivity is closer to that of cytogenetics than other molecular tests. This supplement separates the collection of conventional cytogenetics from FISH at diagnosis. If testing was done via FISH, *those specific questions should be completed*. This section will compare the results from diagnosis with the results of testing at relapse. See the table below for examples of common cytogenetic abnormalities:

Disease	Form/Questions	FormsNet version forms:
AML	Form 2010 Q28-55	http://www.cibmtr.org/DataManagement/DataCollectionForms/Documents/2010/Rev1.0/combine_2010_AML.pdf
ALL	Form 2011 Q18-41	http://www.cibmtr.org/DataManagement/DataCollectionForms/Documents/2011/Rev2.0/combine-2011%20ALL%20r2.pdf
MDS	Form 2014 Q33-61	http://www.cibmtr.org/DataManagement/DataCollectionForms/Documents/2014/Rev1.0/combine_2014_MDS.pdf

DIRECTIVE(S): Indicate whether cytogenetic testing was performed.

Q2 or Q20 LK
Q2 MDS: *Results of test at diagnosis, before the start of / treatment:*

DIRECTIVE(S): If results were 46, XX for a female recipient or 46, XY for a male; answer 'no abnormalities'. If not normal, 'yes, abnormalities identified', unless the abnormality was random (only 1 copy). If the cells were not able to divide, the result comes back 'no evaluable metaphases'.

Q3-19 or Q21-36 LK/ Q3-19 MDS:	Specify abnormalities: {AML Q31-45} {ALL Q13-26} {MDS Q29-44} {120-Insert I, Q21a-d}{120-Insert II, Q12a-f} {120-Insert V, Q29a-o}

DEFINITION:

Under the microscope a chromosome looks a lot like the letter X. The top half of the chromosome (X) is known as the short arms and is designated by the letter 'p' (for petite). The bottom is known as the long arms and is designated by the letter 'q'. Abnormalities may involve the entire chromosome, either missing (monosomy) or duplicated (trisomy). If a portion of the chromosome is defective it is a structural abnormality.

An entire missing chromosome (monosomy) and deletion from an arm of a chromosome may be collected in the same question for the same chromosome, e.g. Q15 '-5' represents monosomy 5, a missing chromosome 5. "5q-" represents the deletion of material from the q arm of chromosome 5 (may also appear as del(5q)).

An abnormal 3q, 11q, 16q includes any type of abnormality involving the q arm of the specified chromosomes.

Translocation, designated by "t", indicates that a piece of an arm from one chromosome broke off and reattached to another chromosome. When 2 sets of parenthesis describe the translocation, the first set identifies the chromosome numbers; the second set shows the breakpoints. CIBMTR Forms do not collect the breakpoint region; do not report these in "other" (e.g. t(9;22)(q34;q11): the translocation is between chromosome 9 & 22. The breakpoints are q34 and q11 and are not reported to CIBMTR.

Do not confuse chromosome number with breakpoint region. The chromosome is always indicated before the chromosome arm (p or q), and the breakpoints are given after the arm.

For more detailed information on reporting cytogenetics, see the presentation by Willis Navarro, MD, at the Clinical Research Professionals Data Management Conference during the 2010 BMT Tandem Meetings: http://www.cibmtr.org/Meetings/Materials/CRPDMC/Pages/feb10Navarro2.aspx

DIRECTIVE(S):

If the recipient was transplanted for AML, use Q15-31; for ALL use Q33-48; for MDS use q19-35 to report conventional cytogenetic testing results.

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Q37-69 LK / Q20-38 MDS:	*Was genetic testing using FISH performed at diagnosis*?

DEFINITION:

FISH (Fluorescent in situ Hybridization) is a method of looking for the same abnormality (as conventional cytogenetics) in typically 200-500 cells, but via a fluorescent tag on the corresponding gene. FISH was reported in the cytogenetic section of the legacy Forms, not molecular, as the level of sensitivity is closer to that of cytogenetics than other molecular tests. *This supplement separates the collection of conventional cytogenetics from FISH at diagnosis.* If testing was done via FISH, *these specific questions should be completed*. This section will compare the results from diagnosis with the results of testing at relapse.

DIRECTIVE(S):

If abnormalities were identified at diagnosis via FISH, report the specifics in Q50-81 LK / 37-54 MDS. See details at Q14.

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Q70-91 LK/ Q39-55 MDS: Were tests (e.g., PCR) for BCR/ABL or other molecular markers done at any time prior to conditioning?{ALL Q60}. *Also answer this question for AML and MDS.*

DEFINITION: Molecular testing is a very sensitive PCR test that can detect up to 1 cell in 10^5 or 10^6; it is much more sensitive than cytogenetics or FISH. This question will compare the results from diagnosis with the results of testing at relapse.
The CIBMTR legacy ALL Disease Insert had a few specific molecular testing questions, AML/MDS did not. If molecular testing was done for AML/MDS, this question is considered supplemental and must be completed.

DIRECTIVE(S): Indicate whether molecular testing was performed. If yes, also provide the results. The known genetic markers for MDS/Leukemia are given. If your markers do not match, check for a typo on the report.

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Post-HSCT Information

FORM ABBREVIATION KEY

These data correlate to the Report Form that documented the first Post-HSCT #1 relapse.

Correcting data from:
AML = 095-AML p7, Qs.129-134, or 095-AMLFU p1-2, Qs.11-16, go to Sup Q.92-99.
ALL = 095-ALL p6, Qs.109-114, or 095-ALLFU p1-2, Qs.11-16, go to Sup Q.92-99.
MDS = 095-MDS p7, Qs.106-110 or 095-MDS-FU p1, Qs.5-6 go to Sup Qs.56-61, 63.
130 = NMDP Form 130,530,630 p11, Qs.99-100, submit E.C. Form and go to Sup Qs by disease as above.
NMDP Form 140,540,640 p11, Qs.94-95, submit E.C. Form and go to Sup Qs by disease as above.
NMDP Form 150,550,650 p6, Q.35, submit E.C. Form and go to Sup Qs by disease as above.

If not correcting data, go to Sup Qs AML/ALL Q92, 98, 100-103; MDS Q62-71

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Q92 LK / Q56 MDS: Did the disease (AML or ALL) (MDS) relapse post-HSCT #1?

DEFINITION: Remission criteria:
1. Morphologic (hematologic) remission = less than 5% blasts with normal cellularity and normal CBC
2. Cytogenetic remission: normal cytogenetics (diploid)
3. Molecular remission: undetectable (if applicable)

DIRECTIVE(S): All must meet the morphologic (hematologic) criteria for CR and then relapse post-HSCT #1. If the recipient was never in CR post-HSCT, they cannot be reported as having a relapse without an explanation.

Answer should match any previously submitted data from 095-AML or NMDP follow-up forms regarding disease relapse after HSCT #1, date of (post-HSCT) relapse, and site/s of relapse corresponding to that date. For more detailed instructions regarding how to make corrections, refer to the general instructions at the beginning of this document.

Answer option #2, yes, therapy-induced complete remission after persistent or recurrent leukemia posttransplant, requires some thought. This option applies at this time point only if the remission was achieved with therapy not including a DCI/DLI or subsequent HSCT. Depending on when the legacy Report Form was cut off, this answer may need modification in order for the recipient to remain in the study. If the only therapy given for

the relapse was DCI, use option 3, 'yes' relapse or persistent disease. The remission achieved by the DCI will be collected at the end of this supplement.

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Q57 MDS: Most recent posttransplant disease status {MDS Q106} {130 Q98} (refers to relapse post-HSCT #1):

DEFINITION: Remission criteria:
1. Morphologic (hematologic) remission = less than 5% blasts with normal cellularity and normal CBC
2. Cytogenetic remission: normal cytogenetics (diploid)
3. Molecular remission: undetectable (if applicable)

DIRECTIVE(S): All must meet the morphologic (hematologic) criteria for CR and then relapse post-HSCT #1. If the recipient was never in CR post-HSCT, they cannot be reported as having a relapse without an explanation.

Answer should match any previously submitted data from 095-MDS or NMDP follow-up forms regarding disease relapse after HSCT #1, date of (post-HSCT) relapse, and site/s of relapse corresponding to that date. For more detailed instructions regarding how to make corrections, refer to the general instructions at the beginning of this document.

1[] Relapse

2[] Complete remission after posttransplant relapse
Answer option #2, requires some thought. This option applies at this time point only if the remission was achieved with therapy not including a DCI/DLI or subsequent HSCT. Depending on when the legacy Report Form was cut off, this answer may need modification in order for the recipient to remain in the study. If the only therapy given for the relapse was DCI, use option 1, yes, relapse. The remission achieved by the DCI will be collected at the end of this supplement.

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Q93 LK /
Q58 or 59 MDS: Date of relapse {AML Q130} {ALL Q110} {MDS Q107 or 108} {130 Q99}

DEFINITION: Date of relapse usually corresponds to the first date a bone marrow biopsy was performed that meets the criteria of >5% blasts with abnormal cellularity and /or an abnormal CBC. If other sites were involved, report as appropriate.

DIRECTIVE(S): If multiple dates appear on the biopsy report, note the date the biopsy was performed, not the date the lab ran the test or the document was dictated or transcribed. If the date is documented in correspondence from another physician and the precise date is not given, please estimate the date according to the information provided, e.g. 'day' is not given; use the day '15' as long as it chronologically fits with other known dates such as therapy start/stop dates, etc.

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Q60-61 MDS: Treatment given {MDS Q109} **NOTE:** *Report in Sup R02-09MDS Qs78-97*
Date of remission {MDS Q110} MM-DD-YYYY

DIRECTIVE(S): If answer option #2 is selected for MDS Q2, these two additional questions apply. Report the treatment given to achieve the CR in supplemental questions 78-97. Also include the date CR was achieved *as long as it was not achieved due to a DCI/DLI or subsequent HSCT.*

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Site of recurrent AML or ALL or MDS:

Q94 LK / Q62 MDS: Bone marrow {AML Q131} {ALL Q111} {130 Q100a}

DIRECTIVE(S): If the bone marrow biopsy meets the criteria of >5% blasts with abnormal cellularity and/or an abnormal CBC (including peripheral blood), select 'yes'.

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Q63 MDS Blasts in marrow {MDS Q115}

DIRECTIVE(S): From the bone marrow report, indicate the percentage of blasts in the marrow at relapse. If the 'most recent test' captured the relapse at the time of the report, {MDS Q115} may indicate the percentage of blasts at relapse. If the 'most recent test' occurred after the relapse, then report the percentage of blasts at the time of relapse in this supplement; the data will not match what was reported in {MDS Q115}.

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Q95 LK / Q64 MDS: CNS (Central Nervous System) {AML Q132} {ALL Q112} {130 Q100b}

DEFINITION: Leukemia may be detected in Cerebral Spinal Fluid (CSF) or the brain.

DIRECTIVE(S): If leukemic cells are found in the CNS, indicate 'yes'.

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Q96 LK: Testes {AML Q133} {ALL Q113} {130 Q100c}

DIRECTIVE(S): If leukemic cells are found in the testes, indicate 'yes'.

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Q97-99 LK/ Q65-67 MDS: Other / Specify {AML Q134} {ALL Q114} {130 Q100d}

DIRECTIVE(S): If disease is detected somewhere other than the marrow, blood, CNS, or testes, report here. *If detected in the skin, select LK Q7/ MDS Q11, but do not also report on the 'specify' line (text field).*

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Studies obtained from peripheral blood or marrow at time of relapse post-HSCT #1 (Supplemental Form questions):

Q100 LK/Q68 MDS *Was flow cytometry tested for blasts?*

DEFINITION: Flow cytometry measures the characteristics of the cells as they pass a laser beam that detects markers on the cells

DIRECTIVE(S): Indicate whether flow cytometry was performed. If yes, also provide the results.

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Q101-103 LK/ Q69-71 MDS *Results:*

DEFINITION: Flow cytometry was tested in either bone marrow, peripheral blood, or both.

DIRECTIVE(S): Indicate the results. Negative, or if at least one source was positive, report the percentage of positive cells, or not tested as applicable.

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Q104-105 LK/ Q72-73 MDS: *Were cytogenetics tested at relapse post-HSCT#1? Results:*

DEFINITION: Conventional cytogenetics were tested at the first relapse of MDS/Leukemia that occurred after HSCT #1.

DIRECTIVE(S): Comparing the 1st relapse cytogenetics to those tested at diagnosis, select the result that applies. Either abnormalities found at first relapse were the same, were different, there were no metaphases to evaluate, or there were no cytogenetic abnormalities found (46, XX or 46, XY).

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Q106-107 LK/ Q74-75 MDS: *Was genetic testing using FISH performed at the time of relapse post-HSCT #1? Results:*

DEFINITION: FISH was done at the first relapse of MDS/Leukemia that occurred after HSCT #1.

DIRECTIVE(S): Comparing the 1st relapse FISH results to those tested at diagnosis, select the answer that applies. Either abnormalities found at first relapse were the same, were different, there were no cells to evaluate, or there were no markers found.

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Q108-109 LK/ Q76-77 MDS: *Were tests for molecular markers done at the time of relapse post-HSCT #1? Results:*

DEFINITION: PCR was done at the first relapse of MDS/Leukemia that occurred after HSCT #1.

DIRECTIVE(S): Comparing the 1st relapse PCR results to those tested at diagnosis, select the answer that applies. Either abnormalities found at first relapse were the same, were different, there were no cells to evaluate, or there were no markers found.

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FORM ABBREVIATION KEY

Correcting data from
AML = 095-AML p7, Qs.135-145, or 095-AMLFU p1-2, Qs.17-27 go to Sup Q.112-116, 121, 125.
ALL = 095-ALL p6,Qs.115-12 or 095-ALLFU p1-2, Qs.17-27 go to Sup Q.112-116, 121, 125.
MDS = 095-MDS p7, Qs.109-110 or 095-MDS-FU p1, Qs.5-6 go to Sup Q80-84, 89, 93, 97.
130 = NMDP Form 130,530,630 p11, Qs.101-102 submit E.C. Form and go to Sup Q. by disease as above.
NMDP Form 140,540,640 p11, Qs.96-97 submit E.C. Form and go to Sup Q. by disease as above.
NMDP Form 150,550,650 p6, Q.35submit E.C. Form and go to Sup Q. by disease as above.

If not correcting data, go to Sup Qs. as per the disease above.

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Q110 LK / Q78 MDS: Was therapy given after this post-transplant relapse (but before DCI/DLI)? {AML Q135} {ALL Q115} {MDS Q109} {130 Q101}

DIRECTIVE(S): If the relapse was treated, indicate the therapy used. In order to qualify for this study, a DCI/DLI must have been used.

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Q111-116 LK/
Q79-84 MDS: Chemotherapy {AML Q138} {ALL Q118} {MDS Q109} {130 Q102b}

DEFINITION: Three subsets of chemotherapy have been described: "common" chemotherapy, *hypomethylating agents (inhibits DNA methylation), and tyrosine kinase inhibitors (TKI). Examples of the latter two are given in the Form. These questions are supplemental.*

DIRECTIVE(S): If chemotherapy was used, also indicate which subtype.

Table 1 Q17 Common systemic therapy for AML with alternate drug names

Tretinoin	all-trans retinoic acid	ATRA	Vesanoid(r)
cytarabine	cytosine arabinoside	Ara-C	Cytosar
daunorubicin	Cerubidine		
doxorubicin	Adriamycin	Rubex	
etoposide	VP-16	VePesid	Etopophos
gemtuzumab	Mylotarg		
Idarubicin	Idamycin		
intrathecal therapy**			
mitoxantrone	Novantrone		
thioguanine	6-TG		
topotecan	Hycamtin		
Systemic therapy not listed above	Check alternate therapy names first. Print neatly on the blank line		

**Note: The term intrathecal refers to a route of administration of therapy, not the drugs themselves. Typically Ara-C, MTX and/or hydrocortisone were used and should be reported here if administered intrathecally, not systemically.

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Q117 LK /
Q85 MDS: Donor leukocytes {AML Q141} {ALL Q121} {MDS Q109} {130 Q102e}

DEFINITION: The purpose of DLI therapy is to elicit an immune response via T cells. There may be other types of cells present in the infusion (e.g., a saved bag of cells from the original HSCT collection), but it is critical that the purpose of the infusion was not to repopulate the marrow as in HSCT.

What is not intuitive here is that if DCI/DLI was used to treat the relapse, the Form first reporting DCI/DLI was to be cut off one day prior to the DCI/DLI and a new set of Forms submitted. Therefore, the results from the DCI/DLI would be included in that new set of Forms for cases reported in the CIBMTR legacy system, not NMDP. (Refer to the instructions at the beginning of the Post-HSCT section above for more details.)

DIRECTIVE(S): Yes indicates a leukocyte or lymphocyte infusion to treat relapse.

♦♦♦

Q118-119 LK/ Q86-87 MDS: Growth factors {AML Q143} {ALL Q123} {MDS Q109} {130 Q102g}

DIRECTIVE(S): Yes indicates growth factors (e.g. G-CSF, GM-CSF, IL-3) were part of the strategy to treat relapse.

♦♦

Q120-121 LK/ Q88-89 MDS: Immunotoxins {AML Q140} {ALL Q120} {MDS Q109} {130 Q102d}

Gemtuzumab is a supplemental question.

DEFINITION: Immunotoxins are an alternate name for immunotherapy. There are two main types of immunotherapy. *Active* immunotherapies stimulate the body's own immune system to fight the disease. *Passive* immunotherapies do not rely on the body to attack the disease; instead, they use immune system components (such as antibodies) made in the lab. Examples include:

- monoclonal antibodies (passive immunotherapies)
- cancer vaccines and other active immunotherapies
- non-specific immunotherapies and adjuvants

DIRECTIVE(S): Yes indicates the use of immunotoxins to treat relapse.

♦♦

Q122 LK / Q90 MDS: Interferon alpha {AML Q137} {ALL Q117} {MDS Q109} {130 Q102a}

DIRECTIVE(S): Yes indicates the use of interferon-alpha to treat relapse post-HSCT.

♦♦

Q123 LK / Q91 MDS: Interferon gamma {AML Q136} {ALL Q116} {MDS Q109}

DIRECTIVE(S): Yes indicates the use of interferon-gamma to treat relapse post-HSCT.

♦♦

Q124-125 LK/ Q92-93 MDS: Second HSCT {AML Q142} {ALL Q122} {130 Q102f} {MDS Q109}

Type: 1•• Allogeneic 2•• Autologous

DEFINITION: Typically, a subsequent HSCT to treat relapse involves a preparative regimen prior to the infusion of the cells. If the subsequent infusion was not for a reason relating to ANC recovery, and no preparative regimen was given, consider whether the infusion was a Donor Cellular Infusion (e.g. DLI) rather than a subsequent HSCT. Uncertainty should be brought to the attention of the physician overseeing care of the recipient or send details to the Study CRCs mentioned at the beginning of this manual.

DIRECTIVE(S): Yes indicates a subsequent HSCT infusion to treat the post-HSCT relapse.

♦♦

Q126 LK / Q94 MDS: Withdrawal of immune suppression {AML Q139} {ALL Q119} {MDS Q109} {130 Q102c}

DEFINITION: For allo HSCT, the recipient typically receives prophylaxis to prevent the complication GVHD. As a strategy to treat early relapse, the immune suppression given for GVHD prophylaxis may be withdrawn to induce a graft-vs.-leukemia (GVL) effect.

DIRECTIVE(S): Yes indicates withdrawal of immune suppression to treat relapse.

♦♦

Q127-128 LK/ Q95-96 MDS: Other, specify. {AML Q144} {ALL Q124} {MDS Q109} {130 Q102h}

DIRECTIVE(S): If none of the above categories describes the treatment for relapse, report in "other" and specify what the 'other' therapy was.

♦♦

Q129 LK / Q97 MDS: Was complete remission achieved [before the DCI/DLI]? {AML Q145} {ALL Q125} *Supplemental for MDS*

DEFINITION: Refer to Q1 for the definition of CR.

DIRECTIVE(S): 'Yes' indicates the criteria for CR was met with therapy other than a DCI/DLI or second transplant. This is a change from how the Form was originally completed.

♦♦
♦♦

Pre-DCI Information

In the CIBMTR legacy system if a subsequent HSCT or DCI was performed to treat this relapse, centers should have stopped completing the Follow-up Form and started either a new HSCT Day-100 Report Form (RF) or a DCI RF. **Answers in this section are from the Disease Insert associated with the DLI infusion (do not repeat the data from the Pre-HSCT #1 Disease Insert). Any references in the legacy Form questions to "just prior to conditioning", should be interpreted as "just prior to the DCI/DLI infusion".**

FORM ABBREVIATION KEY

Day-100 RF completed for Subsequent HSCT (not the DCI); contact the study CRCs to confirm participation.
Day-100 RF completed for DCI; if yes, complete remaining Sup Qs. 137, 140-143 LK or 103-107, 110-117 MDS
002-DCIG = DCI RF completed for DCI, if yes, complete remaining Sup Qs. *137, 140-143 LK or 103-107, 110-117 MDS*
If a Day-100 or DCI Report Form was NOT completed for the DCI, answer all Qs.
NMDP answer all Qs.

Hematologic Findings Just Prior to DCI Infusion

Report the last laboratory values prior to the DCI Infusion (preferably within 2 weeks of the infusion).

Q130 LK / Q98 MDS: WBC x 109/L (or 103/mm3) {AML Q85} {ALL Q65} {MDS Q96}

DIRECTIVE(S): If WBC (white blood cell) count is measured in units other than the units $x10^9$/L or $x10^3/mm^3$, please convert before entering.

♦♦

Q131 LK / Q99 MDS: Blasts in blood (by morphology NOT flow) % {AML Q86} {ALL Q66} {MDS Q99}

DIRECTIVE(S): Provide % of circulating WBC that are blasts from a CBC, not flow cytometry.

♦♦♦

Q100 MDS: Cellularity {MDS Q101}

DIRECTIVE(S): From the bone marrow report, was the cellularity decreased, normal, or increased?

♦♦♦

Q101 MDS: Fibrosis {MDS Q102}

DIRECTIVE(S): From the bone marrow report, was fibrosis decreased, normal, or increased?

♦♦♦

Q132-133 LK / Q102 MDS: Blasts in bone marrow (by morphology NOT flow) % / date of bone marrow exam {AML Q87-88} {ALL Q67-68} {MDS Q103}

DIRECTIVE(S): Provide percentage of blasts found in the bone marrow from a bone marrow biopsy or aspirate and the date the study was performed.

♦♦♦

Q134 LK/ Q103 MDS: Was extramedullary leukemia present ***just prior to DCI Infusion*** {AML Q89} {ALL Q69}

DEFINITION: Extramedullary means disease outside the bone marrow or blood.

DIRECTIVE(S): If leukemic cells are found just prior to the DCI infusion in the cerebral spinal fluid (CSF), skin infiltrates, chloroma, lymphadenopathy, splenomegaly, or gum infiltrates indicate 'yes'.

♦♦♦

Q135-138 LK/ Q104-107 MDS: Central nervous system, Other, Specify*, or Skin* {AML Q90-91} {ALL Q70-71}

DIRECTIVE(S): CNS/CSF and skin have specific check boxes, all else report as 'other'.

♦♦♦

Q108 MDS: Did patient have systemic symptoms (fever, sweats, weight loss >10%) just prior to ~~conditioning~~ ***DCI Infusion***? {MDS Q91}

DIRECTIVE(S): Fever, sweats, weight loss >10% are referred to as systemic symptoms. Indicate 'yes' if the recipient had these symptoms at the time of DCI Infusion.

♦♦♦

Q109, 110-111 MDS: Indication for ~~bone marrow transplant~~ DCI {MDS Q104}

DIRECTIVE(S): Although the CIBMTR legacy Form was designed to collect transplant data, for a period of time it was also used to collect data for DCI/DLIs. The wording of the questions may refer to 'transplant', but in this use substitute the word DCI/DLI for the word 'transplant'.

Indicate the reason for [transplant] DCI with the options provided. It is unlikely that a DCI would be given for bone marrow failure as that typically requires stem cells (a subsequent transplant). *If the reason options are not applicable, report the status of MDS (WHO categories), or briefly describe the reason in 'other' if nothing else applies.*

♦♦

Q139 LK / Q112 MDS: Disease status of AML or ALL or MDS ***immediately prior to DLI*** {AML Q117} {ALL Q96} *Supplemental for MDS*

DEFINITION: Remission criteria:
1. Morphologic (hematologic) = less than 5% blasts with normal cellularity and normal CBC
2. Cytogenetic: normal cytogenetics (diploid)
3. Molecular: undetectable
And no other signs/symptoms of disease

If disease status at the time of DCI/DLI is unknown, please provide an explanation in the margin or on a separate sheet.

DIRECTIVE(S): All must meet the morphologic criteria to indicate complete remission.

♦♦

If recipient is not in CR at the time of DLI:

DIRECTIVE(S): Indicate which method/s documented 'not in CR' during the last evaluation prior to the DCI ('yes' – present, 'no' – not present by that method, or 'unknown' – test not done or result was inconclusive).

♦♦

Q140 LK / Q113 MDS: *Disease present by blood and/or bone marrow*

DEFINITION: Greater than 5% blasts present as reported in the bone marrow or blood.

DIRECTIVE(S): If recipient is in relapse, this answer must be consistent with the hematologic findings reported at the top of the page.

♦♦

Q141 LK / Q114 MDS *Disease present by flow cytometry*

DEFINITION: Flow cytometry measures the characteristics of the cells as they pass a laser beam that detects markers on the cells.

DIRECTIVE(S): If recipient is in relapse and disease was detected by flow cytometry, indicate as 'yes'.

♦♦

Q142 LK / Q115 MDS: *Disease present by cytogenetics/FISH*

DEFINITION: Refer to section: Q13LK/Q17 MDS
FISH (Fluorescent in situ Hybridization) is a method of looking for the same abnormality in typically 200-500 cells, but via a fluorescent tag on the corresponding gene. In the legacy reporting system, FISH was reported in the cytogenetic section, not molecular, as the level of sensitivity is closer to that of cytogenetics than other molecular tests.

DIRECTIVE(S): If the recipient was in relapse and cytogenetics/FISH tests were done at the time of relapse, indicate the results in Q142 or 115. If you are unfamiliar with reading/interpreting FISH, please consult with someone at your Center or the Study CRCs for assistance. Cytogenetic and/or molecular remission status is a very important outcome for this study.

♦♦

Q143 LK / Q116 MDS: *Disease present by molecular/PCR*

DEFINITION: Molecular testing is a very sensitive PCR test that can detect up to 1 cell in 10^5 or 10^6. It is much more sensitive than cytogenetics or FISH.

DIRECTIVE(S): If recipient was in relapse and molecular testing was performed at the time of DCI, indicate the results in Q143 or 116. If you are unfamiliar with reading/interpreting molecular tests, please consult with someone at your Center or contact the Study CRCs for assistance.

♦♦

Q144 LK / Q117 MDS: Date this disease state was first achieved {AML Q118} {ALL Q98}
This question is supplemental for MDS.

DEFINITION: Date of CR1 usually corresponds to the first date a bone marrow biopsy was performed that meets the criteria of less than 5% blasts with normal cellularity and a normal CBC. Date of relapse represents not meeting the criteria for CR after having been in CR. If multiple dates appear on the biopsy report, take care to note the date the biopsy was performed, not the date the lab ran the test or the document was dictated or transcribed. If the date is documented in correspondence from another physician and the precise date is not given, please estimate the date according to the information provided, e.g. 'day' is not given; use the day '15' as long as it chronologically fits with other known dates such as therapy start/ stop dates, etc.

DIRECTIVE(S): This date may be well before the evaluation at time of DCI, as it represents the date the status was first achieved, not confirmed, just prior to DCI.

♦♦
♦♦

DCI Information

These data are from the Graft Insert for the DCI-RF (DCIG).
If a DCIG was completed, make corrections if needed, and answer the supplemental Qs 165, 262-271AML/ALL or 138, 235-244 MDS.
If no DCIG, answer all questions.
NMDP answer all questions as no separate Form was requested by NMDP for DCI.

Source of DCI: These questions relate to the Timing of donor cell collection questions as indicated:

Q145 LK / Q118 MDS:	Collected at time of PBSC mobilization and collection {002-DCIG Q15}
DEFINITION:	At the time of collection for the first HSCT, extra cells may be collected and saved as a back-up. These cells can be used for a DCI if no preparative regimen was used prior to infusion and the reason for the re-infusion was to induce an immune effect from the lymphocytes against disease, not re-populate the marrow (e.g. help recovery from treatment or repopulate the marrow from a failed engraftment or graft failure).
DIRECTIVE(S):	Indicate yes if back up cells from the original PBSC collection were used for the purpose of DCI. Timing question should be option #1; if not, please explain.

♦♦

Q146 LK / Q119 MDS:	Negative fraction of CD34 selected PBSC {002-DCIG Q16}
DEFINITION:	When stem cells are collected from PBSC by selecting for the CD34+ cells, the method is referred to as positive selection. The remaining cells are referred to as the negative fraction and contain many lymphocytes.
DIRECTIVE(S):	If the saved negative fraction from CD34+ selection was used for the DCI, indicate as ‘yes’.

♦♦

Q147 LK / Q120 MDS:	Negative fraction of CD34 selected BM {002-DCIG Q17}
DEFINITION:	When stem cells are collected from bone marrow by selecting for the CD34+ cells, the method is referred to as positive selection. The remaining cells are referred to as the negative fraction and contain many lymphocytes.
DIRECTIVE(S):	If the saved negative fraction from CD34+ selection was used for the DCI, indicate ‘yes’.

♦♦

Q148 LK / Q121 MDS:	Apheresis at a different time than collection of PBSC used for allogeneic transplant {002-DCIG Q18}
DIRECTIVE(S):	If the cells used for the DCI are from a separate collection (not the original collection for HSCT), answer ‘yes’.

♦♦

Q149-150 LK/ Q122-123 MDS:	Isolated from a unit(s) of whole blood. Specify number of units. {002-DCIG Q19}
DIRECTIVE(S):	If the cells come from whole blood, answer yes and indicate the number of units.

♦♦

Q151 LK / Q124 MDS: Did donor receive treatment prior to donation to enhance cell collection? {002-DCIG Q35}

DEFINITION: As stem cells are not necessary for a DCI, this question more likely is 'no', unless saved cells from the original HSCT were used. Stem cells do not typically circulate in the blood stream. Therefore, in order to increase the quantity of cells for collection, an agent is frequently given to the allogeneic donor or autologous recipient. The purpose of the agent is to move the stem cells from the bone marrow into the peripheral blood. This practice is often referred to as *mobilization* or *priming*.

DIRECTIVE(S): Answer yes if the donor received a treatment to enhance cell collection.

♦♦♦

Q152-156 LK/ Q125-129 MDS: Growth factors {002-DCIG Q36-40}

DEFINITION: A growth factor is a substance that affects an organism's growth. Examples of growth factors include but are not limited to the following:

- Epidermal growth factor (EGF) {002-DCIG Q39}
- Erythropoietin (EPO) {002-DCIG Q39}
- Fibroblast growth factor (FGF) {002-DCIG Q39}
- Granulocyte-colony stimulating factor (G-CSF) {002-DCIG Q37}
- Granulocyte-macrophage colony stimulating factor (GM-CSF) {002-DCIG Q38}
- Growth differentiation factor-9 (GDF9) {002-DCIG Q39}
- Hepatocyte growth factor (HGF) {002-DCIG Q39}
- Insulin-like growth factor (IGF) {002-DCIG Q39}
- Platelet-derived growth factor (PDGF) {002-DCIG Q39}
- Thrombopoietin (TPO) {002-DCIG Q39}
- Transforming growth factor alpha (TGF-α) {002-DCIG Q39}
- Transforming growth factor beta (TGF-β) {002-DCIG Q39}

DIRECTIVE(S): Common growth factors include G-CSF (filgrastim, Neupogen) and GM-CSF (sargramostim, Leukine). If another growth factor was used, indicate in 'Other' and specify what was given.

♦♦♦

Q157-158 LK / Q130-131 MDS: Other treatment, specify {002-DCIG Q41-42}

DIRECTIVE(S): Answer yes if something other than growth factors were used and indicate what it was on the specify line.

♦♦♦

Q159-160 LK/ Q132-133 MDS: Were the cells cryopreserved? {002-DCIG Q43}

DIRECTIVE(S): Indicate yes if the cells were frozen prior to being infused. All {002-DCIG Q44} or Some {002-DCIG Q44}

♦♦

Q161-162 LK/ Q134-135 MDS: Were any DCIs reported on this Graft Insert manipulated / All or some? {002-DCIG Q48}

DEFINITION: CD34+ selection of a product results in the two fractions: a positive fraction (CD34+) used for HCT and a negative fraction (contains T cells) that may be used for a DCI. Since the negative fraction containing the T cells was the result of a CD34+ selection of the original product, report that the DCI was manipulated.

DIRECTIVE(S): If any part of the product was manipulated in any way prior to infusion, check "yes." **Do not report cryopreservation as a method of manipulation.**

NOTE: Specify all methods used to manipulate the product.

- Report all methods used to manipulate the product at the transplant facility. If the product was shipped to your facility, do not report manipulation of the product performed at the collection center.
- All bags from one mobilization cycle are considered a single product; report all manipulation methods used on any part of the single product.
- Do not report methods of manipulation performed as part of another procedure (e.g., T cell depletion as part of expansion).

♦♦

Specify all methods used to manipulate DCIs reported on this Graft Insert

Q163 LK / Q136 MDS: Dextran-albumin wash {002-DCIG Q50}

DEFINITION: A combination of dextran and albumin may be used while thawing the cells. Studies show improved cell recovery with this method.
http://ash.confex.com/ash/2010/webprogram/Paper27339.html

http://www.celltherapysociety.org/files/PDF/Meetings/Regional/Session_4a-Cryopreservation___CD34_selection.pdf

DIRECTIVE(S): Indicate whether the cells were thawed with a dextran-albumin solution.

♦♦

Q164-165 LK/ Q137-138 MDS: Genetic manipulation (gene transfer/transduction) {002-DCIG Q51} */ Method*

DEFINITION: Genetic manipulation is a promising area of research, and hematopoietic stem cells are promising target cells for gene therapy due to their differentiation and expansion abilities.

DIRECTIVE(S): Indicate if genetic manipulation was used on the product. If yes, the 'method' is a supplemental question.

♦♦

Q166-168 LK/ Q139-141 MDS: CD34+ selection, Method, Manufacturer {002-DCIG Q52-54}

DEFINITION: CD34+ selection is a manipulation method also known as "positive selection." This method collects stem cells that have a CD34+ marker on the surface cell, and is commonly done with a CliniMACS/CliniMax or Isolex machine.
DIRECTIVE(S): Indicate if CD34+ selection was used and the type of machine used.

♦♦♦

Q169-181 LK/
Q142-154 MDS: T cell depletion, Method(s) of T depletion: {002-DCIG Q55-67}

DEFINITION: This method of negative selection manipulation is most commonly used for allogeneic HSCT, as it removes some or all of the T cells to minimize GVHD. The removed T cells may be infused at a later date (e.g., DLI). Methods of T cell depletion may include the use of antibodies.

NOTE: CD34+ Affinity Column Plus Sheep Red Blood Cell Rosetting

CD34+ affinity column plus sheep red blood cell rosetting combines two methods (positive and negative selection) to achieve greater T cell depletion. Sheep erythrocytes adhere spontaneously to human T cells, forming rosettes. The rosettes are then isolated from the rest of the product using Ficoll-Hypaque gradient centrifugation.

DIRECTIVE(S): Indicate if the product was T cell depleted and the method used. If “yes” is selected for {DCIG Q56-58 or 63-64}, indicate the specific antibodies used for T cell depletion in {DCIG Q88-106}.

♦♦♦

Q182-183 LK/
Q155-156 MDS: Other manipulation, specify. {002-DCIG Q68-69}

DEFINITION: Examples include but are not limited to the following:

- Preparation of T regulatory cells
- B cell reduction
- Buffy coat enrichment
- CD133 enrichment
- Monocyte enrichment
- Mononuclear cell enrichment
- PUV treatment

Cryopreservation is NOT considered a method of manipulation.
Do not include cryopreservation or freeze media in the “other” category.

DIRECTIVE(S): Indicate if the product was manipulated using any other method, and specify the manipulation type.

♦♦♦

Q184-202LK/
Q157-175MDS: Were antibodies used during graft manipulation? {002-DCIG Q70-80}

DEFINITION: If antibodies were used during product manipulation, select “yes.”
Method(s) of T depletion:
Various specific antibodies to select or remove specific cell subsets are listed, e.g. Anti-CD2 through Anti-CD52 and Other, specify. {002-DCIG Q70-80}

DIRECTIVE(S): Specify the antibodies used for product manipulation. *Do not leave any responses blank*.

♦♦♦

Q203 LK/Q176 MDS: Patient actual weight {002-DCI Q31}

DEFINITION: The quantity of cells infused may be divided by weight to measure cells/kg infused for analysis.

DIRECTIVE(S): Indicate the recipient's weight (in kilograms or pounds) closest to the time of DCI infusion.

♦♦

Q204 LK /Q177 MDS: Consecutive number of infusions within 28 days of first {002-DCIG Q151}

DEFINITION: Sometimes more than one DCI is performed in less than 28 days. In order to make reporting more efficient, infusions given less than 28 days apart can be included in a single Report Form.

DIRECTIVE(S): Counting the first infusion as one, report how many infusions were given within 28 days, e.g. if the first infusion was the only infusion, then answer 1; if two infusions were given ten days apart, then answer 2; if four infusions were given one week apart, then answer 4.

♦♦

Q205 LK / Q178 MDS: Date of first infusion {002-DCIG Q152}

DIRECTIVE(S): If more than one infusion was received within 28 days, report the date of the first infusion.

♦♦

Q206-232 LK/ Q179-205 MDS: Quantity of cells infused {002-DCIG Q153-179}

DEFINITION: ***Provide Total numbers of cells after processing. Do not report numbers of cells per kg. If cells were cryopreserved, give totals after processing, but before cryopreservation. (Cell processing lab may be able to help sort out this information if it is not clear in the record.)***

DIRECTIVE(S): Carefully record the cell type, quantity, exponent, and/or percentage from the cell processing report.

♦♦

Q233 LK / Q206 MDS: Date of second infusion {002-DCIG Q181}

DIRECTIVE(S): This date must be within 28 days of the first DCI infusion. If only one infusion was received within 28 days, leave this date blank.

♦♦

Q234-260 LK/ Q207-233 MDS: Quantity of cells infused [second infusion] {002-DCIG Q182-261}

DIRECTIVE(S): See Q206-232LK/Q179-205MDS (above).

♦♦

Q261 LK / Q234 MDS: Were more than 2 DCIs given within a 4-week period? {002-DCI Q180}

DEFINITION: Counting DCI/DLI infusions can be confusing. In the legacy data reporting system, in order to not make Report Forms start over for every new DCI/DLI infusion, all DCIs performed over a 28 day period were analyzed as one "DCI event". The quantity of cells infused on each date is important and should not be added together. That is why a second grouping of infused cell doses is available. The page may also be photocopied to report the cell doses from additional DCI/DLI infusions given within 28 days of the first DCI/DLI reported on this Supplemental Form.

DIRECTIVE(S): Indicate whether the recipient received more than 2 DCIs within 28 days of the first DCI. This is an indicator for multiple copied pages of data for this recipient. Answer 'yes' if the answer to Q108 LK/Q121 MDS is 3 or more.

Note: If more than 2 DCIs given within a 4-week period, copy this page and provide additional infusion data

♦♦

Q262-267 LK/ Q235-240 MDS: *If >1 DCI infusion was given, indicate why.*

DIRECTIVE(S): If data is filled for Q138-165 LK / Q151-178 MDS, this question should be answered; if the DCI/DLI occurred on 1 day only, leave this question blank. The infusions should be within 28 days of the first. If the infusions were more than 28 days apart, in the legacy system the Report Forms would have started over. The most common reasons for multiple DCIs are listed. If 'other reason', briefly summarize in the text field.

♦♦

Q268-269 LK/ Q241-242 MDS: *Was a DCI given > 28 days from the first?* (see Sup-R02-09 Q205LK / Q178 MDS)

DEFINITION: At the time of the legacy data collection, all DCIs within 28 days of the first were considered as one DCI event. A DCI more than 28 days from the first required the Report Forms to start over. The disease status data in the "Post-DCI" section will need to be cut off one day prior to the DCI that occurred >28 days from the first and reported rather than taking the data to the present (or time of death).

DIRECTIVE(S): If a DCI occurred > 28 days from the first DCI, indicate 'yes' and record the date of the DCI.

♦♦

Q270-271 LK/ Q243-244 MDS: *Was a subsequent HSCT given after the first DCI?* (see Sup-R02-09 Q109LK / Q122 MDS)

DEFINITION: At the time of the legacy data collection, a subsequent HSCT required the Report Forms to start over. The disease status data in the "Post-DCI" section will need to be cut off one day prior to the start of the preparative regimen for the subsequent HSCT and reported rather than taking the data to the present (or time of death).

DIRECTIVE(S): If a subsequent HSCT occurred after the first DCI, indicate 'yes' and record the date of the subsequent HSCT.

♦♦
♦♦

“Post-DCI Information”

“Post-DCI Details” ***Answers are from the disease insert associated with the DLI infusion.***

DIRECTIVE(S): Complete Follow-up data on this supplemental Form up to the most recent follow-up for the recipient*. Any Follow-up due on an AML Disease Specific Post-HSCT Form will also be due according to your Center Forms Due Report.

*The timeline below represents how far follow-up should be reported on Sup-R02-09:

- DX = diagnosis of AML/ALL/MDS
- HSCT#1 = the 1st HSCT takes place
- Relapse = relapse occurs post-HSCT #1
- DCI = at some point a DCI/DLI is used to treat the post-HSCT relapse.
- Follow-up would continue up to the present or death UNLESS another DCI/DLI was given more than 28 days from the first one or the recipient has a subsequent HSCT (HSCT#2). In either of those scenarios, cut off the post-DCI follow-up reporting on this Supplemental Form one day prior to the DCI/DLI *or* one day prior to the preparative regimen for the subsequent HSCT (#2) *or* one day prior to HSCT#2 if no preparative regimen was used.

Timeline*:

____DX______HSCT#1___________relapse___DCI___continue to the present** (or death),

**unless >28 days a new DCI or HSCT#2, then stop follow-up / Sup R02-09.

♦♦

Q272 LK/Q245 MDS Status of disease at time of this report or at time of death {AML Q129} {ALL Q109} {MDS Q106} {130 Q98}

DEFINITION: 1 ❑ In continuous complete remission post-HSCT / 1 ❑ Continuous complete remission

If the status of leukemia/MDS at the last look *prior to DCI #1* was complete remission *or* CR was achieved at the first look post-DCI#1 **and** the recipient remained in CR up to the most recent evaluation, select ‘continuous CR post-HSCT’. (Legacy Form referred to HSCT, not DCI. Please “read” as “post-DCI”.)
(Note: if a subsequent HSCT occurred, these data should be cut off just prior to the disease evaluation, before the subsequent HSCT).

Remission criteria:
1. Morphologic (hematologic) (remission) = less than 5% blasts with normal cellularity and normal CBC
2. Cytogenetic (remission): normal cytogenetics (diploid)
3. Molecular (remission): undetectable

DEFINITION 2 ❑ Therapy-induced complete remission after persistent or recurrent leukemia post-HSCT /
4 ❑ Complete remission after posttranslant relapse

This option reflects one of the following scenarios:
The status of leukemia/MDS at the last look prior to DCI #1 was complete remission but the recipient relapsed post-DCI #1, received post-DCI therapy (not including a subsequent HSCT) or DCI more than 28 days from the first DCI) and is now in CR.
OR

The status of leukemia/MDS at the last look prior to DCI #1 was *not* complete remission, but CR was achieved post DCI/DLI (not including a subsequent HSCT or DCI/DLI more than 28 days from the first DCI) and is now in CR.
OR
The status of leukemia at the last look prior to DCI #1 was *not* complete remission, CR was not achieved post DCI/DLI but the recipient received post-DCI therapy (not including a subsequent HSCT or DCI/DLI more than 28 days from the first DCI) and is now in CR.

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DEFINITION: 3 ❑ Relapse or persistent disease ./ 2 ❑ Persistent disease / 3 ❑ Relapse

The recipient had persistent leukemia/MDS post-DCI #1 or leukemia/MDS recurred post-DCI #1.

DIRECTIVE(S): Report the most recent post-HSCT #1 disease status at last contact if alive or at time of death if not, unless the recipient had a subsequent HSCT or a subsequent DCI more than 28 days from the first DCI/DLI reported on this supplement. The most recent/current disease status on this supplement should be cut off prior to any subsequent HSCT or DCI/DLI more than 28 days from the first DCI/DLI indicated on this Form.

♦♦

Q273 LK/Q246 MDS: Date of relapse {AML Q130} {ALL Q110} {MDS Q107 or 108} {130 Q99}

DIRECTIVE(S): If AML, ALL or MDS recurred after the DCI/DLI, report the date relapse was documented. For persistent disease, select the box for 'Never in remission' (post-DCI/DLI).

♦♦

Q274-279 LK/
Q247-251 MDS: Site of recurrent AML or ALL, or MDS {AML Q131-134} {ALL Q111-114} {130 Q100a-d}

DEFINITION: Bone marrow, CNS, testes, other: specify*, skin.*

DIRECTIVE(S): If the disease relapsed or was persistent after the DCI/DLI, indicate the site/s involved at the time of this report.

♦♦

Q252-254 MDS Most recent post ~~transplant~~ DCI/DLI bone marrow examination {MDS Q112-115}

DIRECTIVE(S): From the bone marrow report, indicate the date of exam, status of marrow cellularity, and the percentage of blasts in the marrow from an aspirate or biopsy, not flow cytometry.

♦♦

Q280 LK/Q255 MDS: Date of latest assessment for the status Q272 LK / Q245 MDS

DEFINITION: Legacy Report Forms included a Core or CoreFU Insert on which a last contact date was reported. The last contact date was also to represent the date of the patient status evaluation. Sup-R02-09 does not include a Core or CoreFU Insert; therefore this date represents at what point the data is cut off for this Form. This second "Post" evaluation at

the end of the Supplemental Form is from the period of time after the DCI/DLI. The way DCI data is collected in FormsNet2 is different. If you have any questions about completing this study request, please do not hesitate to ask.

DIRECTIVE(S): Indicate the date the appropriate disease evaluation was done for Sup R02-09.

The data on Sup AML/ALL p15 or Sup MDS p14 are not limited to the first 100 days post-DCI/DLI. If you need to correct data from a previously submitted 095-AMLFU, 095-ALLFU, or 095-MDSFU, please select the box for making a correction, but also list the Date of Report on page 1 of the Follow-up you are correcting and note that date in the margin of the Supplemental Form.