CIBMTR MANUAL
Supplemental Form: AML-M3/APML
(Sup-APM)

General Instructions for Sup-APM

Questions regarding this supplemental Form should be directed to the Study CRC's:
Milwaukee campus: Kavita Bhavsar - kavitab@mcw.edu
Minneapolis campus: Jill Thompson – jthomps2@nmdp.org

This is a supplement to report forms previously submitted to CIBMTR (formerly IBMTR/ABMTR) and NMDP. Nearly every question on this supplemental form has already been answered by your center. Although it looks long, very few questions are new and the questions are specifically related to APML. **Only 10% of the questions on this 11-page form are new**; the rest are for confirming previously reported data. We only ask that you review the data already submitted to CIBMTR and confirm that it is correct. Each section is preceded by a checkbox where you can confirm that the data within that section were indeed correct when originally reported to CIBMTR/NMDP.

- `New questions are designated by font type "Courier New".`
- Questions for confirmation are in font type "Arial".

Confirming Previously Submitteed Data

- The confirmation questions in Arial font were asked on Report Forms and Inserts that you previously submitted to CIBMTR (formerly IBMTR/ABMTR) or NMDP, as noted on the suppplemental form. To ensure accuracy of data and consistency across forms, please compare the answers you write on this form to the recipients' medical records as well as your copies of previously submitted forms.
- If you had submitted forms using Stem Soft export, please refer to your Stem Soft software.
- If you are missing copies of previously submitted CIBMTR legacy paper forms, please contact Jill or Kavita (see page top) to request copies of your old forms.
- If an answer on a previously submitted form does not match the recipient medical record, tick the correcting data box, follow the instruction on the supplemental form, and:
  - For CIBMTR legacy patients, corrections are made on this form only. For your reference, the question number from the legacy 095-Form is given in {} brackets for each question to be confirmed.
  - For NMDP legacy patients, complete Error Correction Forms for any data that does not match the medical record. Please write the study number LK04-01 on the Error Correction Form so that it is identifiable as part of this study and processed correctly. Legacy error correction forms can be found at https://network.nmdp.org/FORMS/data_collection_forms_idx.pl. Mail or fax the completed Error Correction form to your campus of CIBMTR.

If you do not need to make corrections to the legacy data, tick the appropriate checkbox on the supplemental form and skip to the supplemental data questions identified by the special font.

Some older versions 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 as directed above.

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.

DATA ELEMENT: NMDP Recipient ID: | | | | - | | | | - | |

DIRECTIVE(S): The recipient Identification 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.

DATA ELEMENT: Recipient Local ID (NMDP only): | | | | | | | | | | |

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

DATA ELEMENT: 1. Date of HSCT for which this form is being completed: | | | | | | | | |

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

DATA ELEMENT: 2. Today's Date: *(MMDDYYYY)* | | | | | | | | |

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

DATA ELEMENT: Date Received: *(MMDDYYYY)* | | | | | | | | |

DIRECTIVE(S): Date Sup-APM arrives at CIBMTR (your assigned campus).
Leave this field blank.

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.
If the HSCT was facilitated by NMDP, leave this field blank.

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 visit http://www.cibmtr.org/DATA/Legacy_Data/DOCS/DMManual.pdf (Section 1-E, *Assignment of Team & Patient Identification Numbers*). If the HSCT was facilitated by NMDP, leave this field blank.

DATA ELEMENT: (CIBMTR use only) form ID #: –

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.

DATA ELEMENT:

Registry Use Only

Sequence Number:

Date Received:

DIRECTIVE(S): Leave these fields blank.

DATA ELEMENT:

Pre-HSCT Information

DEFINITION: All questions in the Pre-Hematopoietic Stem Cell Transplant (HSCT) section refer to the period of time prior to the preparative regimen for the recipient's first HSCT.

DATA ELEMENT:

Disease Assessment at Diagnosis

3. What was the histological subtype at diagnosis?

1 ❑ M3

2 ❑ M3V

8 ❑ Unknown

DEFINITION: *Source:* http://www.hmds.org.uk/aml.html

FAB TYPE	BLAST CELLS	MATURING CELLS	IMPORTANT DIAGNOSTIC TESTS
M3	Granular or hyper-granular promyelocytes. Bundles of Auer rods. Bilobed nuclei.	Neutrophils often normal, occasionally dysplastic. erythroid precursors and megakaryocytes - no significant abnormalities.	Cytochemistry: Heavy MPO or SBB staining, strong CAE positivity. Immunofluorescence for PML nuclear protein. Cytogenetics: RT-PCR for t(15;17) and PML/RARa transcripts.
M3V	Variant of M3. Promyelocytes are agranular with deeply basophilic cytoplasm. Bilobed nuclei are a prominent feature.		Cytochemistry, cytogenetics and molecular studies as for classical M3. PML nuclear protein pattern is confirmatory

DIRECTIVE(S): Tick FAB subtype as documented in the medical record at the time of initial AML diagnosis. If not documented anywhere indicate 'unknown'.

DATA ELEMENT: **4.** Was molecular assessment done?

DEFINITION: PCR may be performed at the time of initial diagnosis to detect known molecular markers for APML.

DIRECTIVE(S): If molecular testing was done, further indicate whether **5.** PML-RARα was positive or negative. If other molecular markers were tested, indicate the marker **7.** Specify: and whether results were **6.** Positive 1❑ Negative 0❑

DATA ELEMENT: **Pre-HSCT Details**

8. ***Correcting data from 095-AML p3, Qs.47-56? If yes, check here ❑, and go to Q.9. If no, check here ❑, and CIBMTR go to Q.20, NMDP go to Q.9.***

DIRECTIVE(S): Answer should match any previously submitted data from 095-AML regarding all systemic therapy received prior to achieving first complete remission and prior to HSCT #1. For more detailed instructions regarding how to make corrections, refer to the General Instructions at the beginning of this document.

NMDP Disease Forms did not collect this information; please provide at this time (Qs9-21).

Table 1 Common systemic therapy for AML with alternate drug names

Qs11-13	cytarabine	cytosine arabinoside	Ara-C	Cytosar	1 gm/m^2/d = 1000 mg/m^2/d
Q14	daunorubicin	Cerubidine			
Q15	doxorubicin	Adriamycin	Rubex		
Q19	etoposide	VP-16	VePesid	Etopophos	
Q19	gemtuzumab	Mylotarg			
Q16	idarubicin	Idamycin			
Q19	intrathecal therapy**				
Q17	mitoxantrone	Novantrone			
Q10	thioguanine	6-TG			
Q19	topotecan	Hycamtin			
Q19	Systemic therapy not listed above Check alternate therapy names first. Print neatly on the blank line				
Q20	tretinoin	all-trans retinoic acid	ATRA	Vesanoid(r)	

**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.

DATA ELEMENT: **21.** Did ATRA syndrome occur with induction?

DEFINITION: Unexplained fever, weight gain, respiratory distress, interstitial pulmonary infiltrates, pleural and pericardial effusion, episodic hypotension and acute renal function. The syndrome develops about 10 days after the start of ATRA. Other names for ATRA syndrome: Retinoic Acid Syndrome (RAS) or APL differentiation syndrome

DIRECTIVE(S): Answer whether Atra syndrome was documented as occurring with any induction attempts that utilized ATRA.

DATA ELEMENT: **22.** ***Correcting data from 095-AML p3, Qs.57-58/NMDP Form 120,520,620 Insert 1 p2, Qs.22-23? If yes, check here ❑, and go to Q.23, NMDP submit E.C Form and go to Q25. If no, check here ❑, and CIBMTR/NMDP go to Q.25.***

DIRECTIVE(S): Answer should match any previously submitted data from 095-AML OR NMDP Form 120/520/620 Insert 1 regarding whether a first complete remission was achieved (prior to HSCT #1) and the date of 1st CR. For more detailed instructions regarding how to make corrections, refer to the General Instructions at the beginning of this document. Complete supplemental Qs.25-31 for all recipients.

DATA ELEMENT: **23.** Was a first complete remission achieved?

DEFINITION: Remission has 3 definitions:

1. Morphologic (hematologic) = marrow with normal maturation of all cellular components, ≤ 5% blasts in the marrow and no signs or symptoms of disease
2. Cytogenetic: normal cytogenetics (diploid)
3. Molecular: undetectable PML-RAR* by qualitative method or quantitative ratio of PML-RAR*/PML = *10-3

DIRECTIVE(S): All must meet the morphologic criteria. It may have taken more than one course of therapy to achieve this CR.

DATA ELEMENT: **24.** Date: ☐☐ ☐☐ ☐☐☐☐ (Month Day Year) 8❑ Date unknown

DIRECTIVE(S): 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 normal CBC. 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.

DATA ELEMENT: **25.** Were cytogenetics/FISH tested?

DEFINITION: Cytogenetic tests look at chromosomes in the cells, typically about 20 cells, for any abnormalities. Those specific to APML are t(15;17), t(8;21), inv(16), and any abnormality involving 11q23. 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 is reported in the cytogenetic section, not molecular as the level of sensitivity is closer to that of cytogenetics than other molecular tests. **26.** Cytogenetic CR? Any complete cytogenetic remission (no cells with Ph Chromosome positivity by FISH or conventional cytogenetics) is a subset of major cytogenetic response (remission), where major cytogenetic response includes patients with complete cytogenetic CR (0% Ph positive) and partial cytogenetic CR (1-35% Ph positive cells) response.

DIRECTIVE(S): If 1st CR was achieved and cytogenetics/FISH tests were done at the time of CR1, indicate the results in Q26. 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.

DATA ELEMENT: **27.** Was molecular testing performed?

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): Indicate whether molecular testing was performed at 1st CR. If you are unfamiliar with reading/interpreting molecular tests, please consult with someone at your Center or contact the Study CRCs for assistance.

DATA ELEMENT: **28.** Remission achieved by qualitative testing?

DEFINITION: Some PCR results simply report "positive/detectable but not quantifiable" or "negative/not detected". These are qualitative results that do not try to measure the amount of PML-RARα in a sample

DIRECTIVE(S): Tick "yes" if PCR result indicates an adequate sample was tested and PML-RARα was "negative" or "not detected." Cytogenetic and/or molecular remission status is a very important outcome for this study.

DATA ELEMENT: **29.** Was quantitative testing done? **30.** Test method:

DEFINITION: Some PCR tests report the actual amount of PML-RARα in a sample, usually not "0".

DIRECTIVE(S): If quantitative molecular testing was done, indicate the test method on the specify line. Cytogenetic and/or molecular remission status is a very important outcome for this study.

DATA ELEMENT: **31.** Result:

☐☐☐☐ copies, ***or*** ratio: ☐☐.☐☐ x 10☐☐

or if result not available, was remission achieved?

DEFINITION: Quantifiable measure of PML-RARα should be reported at levels ranging from 100 to $*10^{-4}$.

DIRECTIVE(S): Report either the # of copies of PML-RARα detected, the ratio from which the number of copies was derived, or if quantitative testing done but the value was not documented, indicate molecular remission achieved.

DATA ELEMENT: **32.** ***Correcting data from 095-AML p4, Qs.60-69? If yes, check here ❑, and go to Q.33. If no, check here ❑, and CIBMTR go to Q.44, NMDP go to Q.33.***

DIRECTIVE(S): Answer should match any previously submitted data from 095-AML regarding ***all*** systemic therapy received *after achieving 1st CR for the purpose of consolidation* and prior to HSCT #1. For more detailed instructions regarding how to make corrections, refer to the General Instructions at the beginning of this document. If no corrections, proceed to the supplemental data Q44.

NMDP Disease Forms did not collect this information; please provide at this time (Qs33-44).

Refer to Table 1 Common systemic therapy for AML with alternate drug names at Q8 in this Manual.

DATA ELEMENT:

45. ***Correcting data from 095-AML p4, Q.71? If yes, check here ❑, and go to Q.46. If no, check here ❑, and CIBMTR go to Q.47, NMDP go to Q.46.***

DIRECTIVE(S): Answer should match any previously submitted data from 095-AML regarding ***all*** systemic therapy received *after achieving 1st CR for the purpose of maintenance* and prior to HSCT #1. For more detailed instructions regarding how to make corrections, refer to the General Instructions at the beginning of this document. If no corrections, proceed to the supplemental data Q47.

NMDP Disease Forms did not collect this information; please provide at this time (Q46).

Refer to Table 1 Common systemic therapy for AML with alternate drug names at Q8 in this Manual.

DATA ELEMENT:

48. ***Correcting data from 095-AML p4, Qs.72-77/NMDP Form 120,520,620 Insert 1 p3, Qs.24-25? If yes, check here ❑, and CIBMTR go to Q.49, NMDP submit E.C. Form and go to Qs.51-63. If no, check here ❑, and CIBMTR go to Q.52, NMDP go to Q.51.***

DEFINITION: For definitions of remission and testing, see Q23-31. Note: if 1st CR was never achieved, the patient cannot be reported as having relapsed without an explanation.

DIRECTIVE(S): Answer should match any previously submitted data from 095-AML/NMDP Form 120 Insert 1 regarding **49.** Did a relapse (marrow or extramedullary) occur prior to preparative regimen? (and prior to HSCT #1). For more detailed instructions regarding how to make corrections, refer to the General Instructions at the beginning of this document. If no corrections, legacy CIBMTR centers should proceed to the supplemental data Qs52-59. Legacy NMDP centers should continue with Qs51-63 as legacy NMDP disease inserts did not collect data on the site of 1st relapse (bone marrow (includes blood), CNS, testes, and other sites, e.g. skin).

DATA ELEMENT:

64. ***Correcting data from 095-AML p4, Qs.79-84/NMDP Form 120,520,620 Insert 1 p3, Qs.27-28? If yes, check here ❑, and CIBMTR go to Q.65, NMDP submit E.C. Form and go to Qs.66. If no, check here ❑, and go to Q.66.***

DIRECTIVE(S): Answer should match any previously submitted data from 095-AML/NMDP Form 120 Insert 1 regarding treatment after 1st relapse. If no relapse occurred pre-HSCT, this section should be blank. For more detailed instructions regarding how to make corrections, refer to the General Instructions at the beginning of this document. If no corrections, proceed to the supplemental data Qs67-69, 75, 78-79.

DATA ELEMENT:

Specify treatment given:

	Yes	No	
67.	1❑	0❑	Chemotherapy without anthracycline
68.	1❑	0❑	Chemotherapy with anthracycline

69. Anthracycline dose: ☐☐☐ mg/m² 8❑ Unknown

DEFINITION: http://www.cancer.gov/templates/db_alpha.aspx?CdrID=44916 : **anthracycline** (AN-thruh-SY-klin)

A type of antibiotic that comes from certain types of Streptomyces bacteria. Anthracyclines are used to treat many types of cancer. Anthracyclines damage the DNA in cancer cells, causing them to die. Daunorubicin, doxorubicin, and epirubicin are anthracyclines.

Table 2 Anthracyclines

daunorubicin	Cerubidine	
doxorubicin	Adriamycin	Rubex
idarubicin	Idamycin	

DIRECTIVE(S): If chemotherapy was used indicate whether or not the regimen included anthracyclines (see Table 2) and the grand total dose in the unit mg/m^2 used to treat 1st relapse. Since anthracyclines are cardio-toxic, the total dose is generally tracked.

DATA ELEMENT: **70.** 1❑ 0❑ Immunotherapy

DEFINITION: http://www.cancer.org/docroot/ETO/content/ETO_1_4X_Types_of_Immunotherapy.asp?sitearea=ETO

There are 2 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): This question is provided for data corrections to 095-AML. If yes, indicate whether gemtuzumab was used to treat the 1st relapse. If yes, answer study Qs72-73. One full treatment of gemtuzumab generally consists of 2 days, 2 doses.

DATA ELEMENT: **74.** 1❑ 0❑ Radiation

DEFINITION: Radiation may be used to treat relapse in the CNS or testes

DIRECTIVE(S): This question is provided for data corrections to 095-AML.

DATA ELEMENT: **75.** 1❑ 0❑ Surgery

DIRECTIVE(S): This question is provided for data corrections to 095-AML. Surgery is not a common therapy for relapse.

DATA ELEMENT: **76.** 1❑ 0❑ Other **81.** Specify:

DEFINITION: See Table 1 for a list of systemic/chemotherapy, Note: for the purpose of this study, arsenic trioxide (ATO) and ATRA are listed under “other” in this section. The number of cycles of arsenic may provide important results for this study.

DIRECTIVE(S): If arsenic trioxide (ATO) was given to treat 1st relapse, also answer Q78.

DATA ELEMENT: **HSCT Graft Data Details**

*(If this transplant was autologous, answer **Qs.83-112**. If this transplant was allogeneic, skip to **Q.113**)*

82. *If correcting data from 002-ABM p1, Qs.15-17; p2, Qs.20-38 or 002-APB p1, Qs.17-19; p2, Qs.21-39, check here ❑, and go to Q.83. If no, check here ❑, and go to Qs.92-102.*

DEFINITION: This section is limited to recipients who received autologous HSCT for HSCT #1. This section provides direction for both the auto bone marrow (095-ABM/002-ABM) and auto peripheral blood (095-APB/002-APB) Graft inserts. For more detailed instructions regarding how to make corrections, refer to the General Instructions at the beginning of this document.

DIRECTIVE(S): **NMDP recipient Forms and non-NMDP allogeneic recipients do NOT include these data, skip to Q113.** If there are no corrections for autologous recipients answer supplemental Qs92-95 & 99-102 as applicable.

DATA ELEMENT: **Detected in Circulating Cells*** **Detected in bone marrow prior to harvest***

DEFINITION: **Refers to detection of tumor cells in circulation or bone marrow in the interval between last chemo-therapy and harvest*

DIRECTIVE(S): Qs86-90 & 103-110 refer to legacy data checking whether leukemia was found in the autologous recipient's blood or marrow just prior to the harvest/collection. Chemotherapy was often used to stimulate stem cells to move from the marrow to the peripheral blood prior to collection, hence the directive in the interval between last chemo and harvest.

DATA ELEMENT: **Detected in harvested cells (before purging)**

DEFINITION: The molecular status of the graft prior to purging is a very important data point for this study. Efforts to track down these data are ***GREATLY*** appreciated. For definition information on these data elements please refer to Qs27-31 in this Manual.

DIRECTIVE(S): If leukemia was detected by PCR or other molecular technique in the harvested cells prior to purging, report the results in supplemental Qs92-95 or Qs99-112 as applicable.

DATA ELEMENT:

113. *Correcting data from 095-AML p6, Qs.117-118/NMDP Form 120,520,620 Insert 1 p3, Qs.29-30? If yes, check here ❑, and CIBMTR go to Q.114, NMDP submit E.C. Form and go to Q.115. If no, check here ❑, and go to Qs.114-121*

DEFINITION: Disease status of AML and date the status was achieved just prior to the start of the preparative regimen must agree with data reported in the treatment through relapse sections. For more detailed instructions regarding how to make corrections, refer to the General Instructions at the beginning of this document.

DIRECTIVE(S): If no data correction is needed for disease status of AML, be sure to complete supplemental Qs115-121 if status was complete remission #2 or higher. Remission definitions are listed in Q23 and test information can be found in Qs25-31 in this Manual.

DATA ELEMENT: **Post-HSCT Information**

DEFINITION: Follow-up for this supplement contains data in addition to any Follow-Up Form/s currently due according to the Forms Due lists available within the Forms Net 2 application. The level of detail required by this Supplemental Form is different from that collected on the current version of AMP post-HSCT Disease Forms. Please do not hesitate to contact the Study CRCs listed at the beginning of this document regarding any questions regarding Forms completion for recipients involved in this study.

DIRECTIVE(S): Answer should match any previously submitted data from 095-AML or 095-AMLFU for HSCT #1.

Sup-APM Question	095-AML(12/95)	095-AMLFU	NMDP 130 (12/01)	NMDP 140
Date Relapse #125	130	12	99	94
Bone Marrow #126	131	13	100a	95a
CNS #135	132	14	100b	95b
Testes #136	133	15	100c	95c
Other #137/138	134	16	100d	95d
Therapy #140	135	17	101	96
Chemo #141	138	20	102b	97b
DLI #146	141	23	102e	97e
Growth Factors #147/148	143	25	102g	97g
Immunotoxin #149	140	22	102d	97d
Interferon α #151	137	19	102a	97a
Interferon β #152	136	18	—	—
Second HSCT #153	142	24	102f	97f
Withdrawl Immune-suppression #155	139	21	102c	97c
Other #156-161	144	26	102h	97h
Cr achieved? #162	145	27	—	—
Current status #172	129	11	—	—

NOTE: The data on p8:Q124-180 are not limited to the first 100 days post-HSCT. If you need to correct data from a previously submitted 095-AMLFU please tick the box for making a correction, but also list the Date of Report that is on page 1 of the Follow-up you are correcting and note that date in the margin.

DATA ELEMENT: **Post-HSCT Details**

123. Correcting data from 095-AML p7, Qs.130-134, or 095-AMLFU p1-2, Qs.12-16/ NMDP Form 130,530,630 p11, Qs.99-100, Form 140,540,640 p11, Qs.94-95; or Form 150,550,650 p6, Q.35? If yes, check here ❑, and CIBMTR go to Q.124, NMDP submit E.C. Form and go to Qs.126-134. If no, check here ❑, and go to Qs.127-134.

DEFINITION: **124.** `Did the disease relapse post-HSCT?` For definitions remission and testing see Qs23-31. Note: if recipient was never in CR post-HSCT, they cannot be reported as having relapsed without an explanation.

DIRECTIVE(S): Answer should match any previously submitted data from 095-AML or NMDP follow-up forms regarding disease relapse after HSCT #1; Q125 Date of (post-HSCT) relapse and Qs126-138 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. If relapse occurred in the bone marrow be sure to answer supplemental Qs127-134. If relapse occurred after the last follow-up Form already submitted, that relapse should also be reported here; in effect updating the data. If more than one post-HSCT relapse occurred, this section should be copied and completed for each relapse separately.

DATA ELEMENT:

139. ***Correcting data from 095-AML p7, Qs.135-145, or 095-AMLFU p1-2, Qs.17-27/ NMDP Form 130,530,630 p11, Qs.101-102, Form 140,540,640 p11, Qs.96-97; or Form 150,550,650 p6, Q.35? If yes, check here ❑, and CIBMTR go to Q.140, NMDP submit E.C. Form and go to Qs.142-169. If no, check here ❑, and go to Qs.142-169.***

DIRECTIVE(S): See Qs64-73 in this Manual for information regarding treatment for relapse. Follow instruction at Q139 regarding correcting previously submitted data.

DATA ELEMENT: **142.** 1❑ 0❑ Central nervous system (CNS) (i.e., intrathecal therapy)

DEFINITION: Intrathecal therapy indicates a route of administration into the sheath surrounding the spinal column.

DIRECTIVE(S): Yes indicates treatment for relapse in the CNS.

DATA ELEMENT: **146.** 1❑ 0❑ Donor leukocytes

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. In the legacy CIBMTR reporting system DCI required a separate DCI Report Form (still available on www.cibmtr.org).

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

DATA ELEMENT: **147.** 1❑ 0❑ Growth factors

148. Specify: _____

DIRECTIVE(S): Yes indicates growth factors were part of the strategy to treat relapse.

DATA ELEMENT: **149.** 1❑ 0❑ Immunotoxins

DEFINITION: Immunotoxins are an alternate name for immunotherapy; see Q70.

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

150. 1❑ 0❑ Gemtuzumab

DATA ELEMENT: **151.** 1❑ 0❑ Interferon alpha

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

DATA ELEMENT: **152.** 1❑ 0❑ Interferon gamma

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

DATA ELEMENT: **153.** 1❑ 0❑ Second HSCT

154. Type: 1❑ Allogenenic 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.

DATA ELEMENT: **155.** 1❑ 0❑ Withdrawal of immune supression

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 proph may be withdrawn to induce a graft vs. leukemia (GVL) effect.

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

DATA ELEMENT: **156.** 1❑ 0❑ Other

DIRECTIVE(S): Check whether Qs157-159 apply. If none of the above categories describe the treatment for relapse, report in "other" and specify what the 'other' therapy was.

DATA ELEMENT: **162.** Was complete remission achieved?

DEFINITION: Refer to Qs23-24 for the definition of CR.

DIRECTIVE(S): Yes indicates the criteria for CR was met. If yes, answer Qs163-169 (see Qs25-31 for definitions/directives).

DATA ELEMENT: **Current Status Details**

171. Date of most recent assessment: ☐☐ ☐☐ ☐☐☐☐ Month Day Year

DIRECTIVE(S): ***Important:*** 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.*

DATA ELEMENT: **172.** ***Correcting data from 095-AML p7, Q.129, or 095-AMLFU p1, Q.11/NMDP Form 130,530,630 p11, Q.98; Form 140,540,640 p11, Q.93; or Form 150,550,650 p6, Q.34? If yes, check here ❑, and CIBMTR go to Q.173, NMDP submit E.C. Form and go to Qs.174-180. If no, check here ❑, and go to Qs.174-180.***

DIRECTIVE(S): Follow instructions above if corrections to previously submitted post-HSCT data is required.

DATA ELEMENT: **173.** Disease status at time of this report or at time of death:

DIRECTIVE(S): Report the most recent post-HSCT #1 disease status at last contact if alive or at time of death if not. If death occurred after a subsequent HSCT, cut-off the current disease status prior to the subsequent HSCT.

DATA ELEMENT: 1 ❑ In continuous complete remission post-HSCT

DIRECTIVE(S): If status of APML at the last look prior to HSCT #1 was complete remission, the recipient remained in CR at first look post-HSCT #1 and has remained in CR up to the most recent evaluation tick 'continuous CR post-HSCT'.
(Note: if a subsequent HSCT occurred, these data should be cut-off just prior to the disease evaluation before the subsequent HSCT).
Answer study Qs174-180. Remission definitions are listed in Q23 and test information can be found in Qs25-31 in this manual.

DATA ELEMENT: 2 ❑ Therapy-induced complete remission after persistent or recurrent leukemia post-HSCT

DIRECTIVE(S): This option reflects one of two scenarios:
The status of APML at the last look prior to HSCT #1 was complete remission but the recipient relapsed post-HSCT #1, received post-HSCT therapy (not including a subsequent HSCT) and is now in CR.
OR
The status of APML at the last look prior to HSCT #1 was not complete remission but the recipient received post-HSCT therapy (not including a subsequent HSCT) and is now in CR.
Answer study Qs174-180. Remission definitions are listed in Q23 and test information can be found in Qs25-31 in this manual.

DATA ELEMENT: 3 ❑ Relapse or persistent disease

DIRECTIVE(S): The recipient had persistent APML post-HSCT #1 or APML recurred post-HSCT #1.