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**DOCUMENT NUMBER:** COMM-QA-039 JA9

**DOCUMENT TITLE:**

APBMT Immune Effector Cellular Therapy Safety Endpoints and Toxicity Management Audit JA9

**DOCUMENT NOTES:**

## Document Information

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## Control Information

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| **Author:** BS76 | **Owner:** BS76 |
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# COMM-QA-039 JA9
# APBMT Immune Effector Cellular Therapy Safety Endpoints And Toxicity Management Audit (CONFIDENTIAL)

**Date(s) of Audit:**
**Program(s) Audited:**
**Timeframe for Audit:**
**QSU Representative:**
**APBMT Auditor(s)/SME(s):**

*The Adult and Pediatric Blood and Marrow Transplant (APBMT) Immune Effector Cellular Therapy (IEC) Safety Endpoints and Toxicity Management Audit should be conducted by the Quality Systems Unit (QSU) and/or Subject Matter Experts (SMEs). A qualified representative from QSU will serve as the QSU Representative and verify that the appropriate resolution to any discrepancies are remediated. Select 1 patient from the adult team and 1 patient from the pediatric team annually (calendar year) if the total patient number is less than 10 patients/year/program. If the total patient number is equal to or great than 10 patients/year/program, select 10% of patients from the adult team and 10% of patients from the pediatric team annually (calendar year).* ***There should be minimal 30 days of follow-up on the patient to be included on the audit.*** *If discrepancies are found, document the discrepancy and resolution in the space provided below each question.*

| MRNs included in Audit | |
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| 1. **Correct immune effector cellular therapy product administered against the diagnosis and written order:**<br>• Based on the confirmed diagnosis, was the correct immune effector cellular therapy product utilized?<br>o Check the medication administration record (product administered) against the treatment plan order (product ordered), verify the patient age at the treatment, diagnosis and the type of product.<br>If no, describe the discrepancy and resolution below. | ☐ YES | ☐ NO |
| Describe: | | |

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| 2. **Correct dose administered for the lymphodepleting chemotherapy regimen:**<br>• Was the intended prescribed lymphodepleting chemotherapy dose, route, frequency and infusion duration administered to the patient?<br>o Check the medication administration record (chemotherapy administered) against the treatment plan order (chemotherapy ordered) and/or roadmap.<br>If no, describe the discrepancy and resolution below. | ☐ YES | ☐ NO |
| Describe: | | |

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| 3. **Risk Evaluation and Mitigation Strategy (REMS) training accuracy and completion:**<br>• Was the pharmacist, infusion nurse, STCL staff member, and prescribing physician REMS trained, if applicable?<br>o Check the REMS training record against the individual product specific REMS training requirement, verify the accuracy and the completion of the training.<br>If no, describe the discrepancy and resolution below. | ☐ YES | ☐ NO |
| Describe: | | |

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| 4. **Detection, documentation and management of Cytokine Release Syndrome (CRS) and Neurotoxicity:**<br>• Were the signs and symptoms of CRS and Neurotoxicity monitored and documented during and following the administration of IEC?<br>o Check the STCL-SOP-050 Infusion Form to verify the completion of the documentation.<br>o Review notes for documentation of CRS and neurotoxicity assessments.<br>• Were the patient, caregiver and/or the legally authorized representative given instructions to continue to assess for signs and symptoms of complication when away from the treatment unit or clinic?<br>o Check the discharge instruction/AVS to verify acknowledgement of receipt of the above noted information.<br>• Was the appropriate supportive care and/or treatment administered, if applicable, based upon the grade/severity of CRS and Neurotoxicity during and following the IEC administration?<br>o Verify the diagnosis, grade/severity of the CRS and Neurotoxicity are documented.<br>o Review the medication administration record and/or the treatment plan to confirm that appropriate treatment was given, according to SOP APBMT-COMM-045.<br>If no, describe the discrepancy and resolution below. | ☐ YES | ☐ NO |
| Describe: | | |

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| 5. **Safety Endpoint Documentation:**<br>• Were the endpoints of clinical function documented?<br>o Check the patient medical record to verify the documentation of the follow-up on the patient status at 30 days minimal, if feasible, and at 100 days and 1 year as applicable. Bone marrow, LP or PET scan to be done (at least one), if clinically appropriate.<br>o Check the patient medical record to verify the documentation of the follow-up on the signs, symptoms and diagnoses of CRS and/or Neurotoxicity at 30 minimal if feasible, and at 100 days and 1 year as applicable.<br>If no, describe the discrepancy and resolution below. | ☐ YES | ☐ NO |
| Describe: | | |

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| 6. **Reporting:**<br>• Was an Adverse Experience (AE) reported to the FDA during or following IEC administration? ☐ N/A<br>o Check the reporting record to verify the completion of reporting via fax and receipt of confirmation.<br>o Check the patient report form to verify the patient age at time of treatment, diagnosis, product received, date of product administered, endpoints of clinical function as defined per APBMT program against the patient medical record.<br>If no, describe the discrepancy and resolution below. | ☐ YES | ☐ NO |
| Describe: | | |

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**By signing below, all follow-up items have been resolved, verified, and the audit is now closed.**

**APBMT Auditor's Signature:** _____ **Date:** _____

**QSU Signature:** _____ **Date:** _____

**Department Director or Designee Signature:** _____ **Date:** _____

## Signature Manifest

**Document Number:** COMM-QA-039 JA9 **Revision:** 02

**Title:** APBMT Immune Effector Cellular Therapy Safety Endpoints and Toxicity Management Audit JA9

All dates and times are in Eastern Time.

### COMM-QA-039 JA9 APBMT Immune Effector Cellular Therapy Safety Endpoints and Toxicity Mgt Audit

### Author

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Bing Shen (BS76) | | 02 Apr 2019, 04:40:38 PM | Approved |

### Medical Director

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Joanne Kurtzberg (KURTZ001) | | 02 Apr 2019, 07:00:05 PM | Approved |

### Quality

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Richard Bryant (RB232) | | 03 Apr 2019, 12:18:21 PM | Approved |

### Document Release

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Sandy Mulligan (MULLI026) | | 03 Apr 2019, 04:43:25 PM | Approved |