

DOSE LIMITING TOXICITY (DLT) FORM (6)

*Instructions: This form should be completed weekly after Cycle I and II, until day 30 after start cycle and until ANC recovery, or until start next cycle, or at death, and when any non haematological toxicity CTCAE grade ≥ 4 occurred in 30 days after start treatment, by the local investigator.
Fax a copy of the form to the HOVON Data Center Fax +31.10.7041028 and then send the original form to: HOVON Data Center, Erasmus MC-Daniel den Hoed, P.O. Box 5201, 3008 AE ROTTERDAM, The Netherlands*

Hospital:

Patient study number: | | | | |

DLT form related to induction cycle..... 2 | | 1=cycle I 2=cycle II

Date DLT evaluation was done..... [dd/mm/yyyy] 3 | | | | |

TREATMENT

Has Induction cycle been given (either partially or completely)..... 4 | | 0=no 1=yes

Dose Level Clofarabine..... [mg/m²] 5 | | | fill out 00 mg/m², 10 mg/m², 20 mg/m², 15 mg/m²

Date start related induction cycle..... [dd/mm/yyyy] 6 | | | | |

Date start next treatment..... [dd/mm/yyyy] 7 | | | | |

SURVIVAL STATUS

Date last known to be alive or death..... [dd/mm/yyyy] 8 | | | | |

Survival status..... 9 | | 0=alive 1=dead

Cause of death 10 | | 1=leukemia 5=secondary malignancy
2=pneumonitis 6=deep venous thrombosis
3=other infection* 7=pulmonary embolism
4=hemorrhage 8=other*
9=unknown

*Specify 11

TOXICITY

CTCAE grade ≥ 4 non hematological toxicity occurring within 30 days after

start of this cycle..... 12 | | 0=no 1=yes, fill out next two items

Date onset..... [dd/mm/yyyy] 13 | | | | |

Specification..... 14

ANC recovery

Was ANC recovered to > 0.5x10⁹/L..... 15 | | 0=no 1=yes, fill out date of recovery 2=never below

First date ANC >0.5 x 10⁹/L..... [dd/mm/yyyy] 16 | | | | |

Date: | | | | |

Name:

Signature: