

REGISTRATION AND INCLUSION FORM

Investigator:	Site number:	Hospital	Fax:
Patient Initials: _____	Date of Birth: ____ / ____ / ____ <i>yy mm dd</i>	Date AML Dx: ____ / ____ / ____ <i>yy mm dd</i>	E-mail (<i>investigator</i>)

REGISTRATION (*see page 2 for guidance*)

	Yes	No	Dates & Comments
1. AML with intermediate or poor risk features			
2. Planned to receive RIC or consolidation chemo?			
3. Signed informed consent			Date (yyymmdd)
4. MUD RIC planned? [<i>if potential sibling donor(s) will turn out not being eligible, or if there are no potential sibling donor(s)</i>]			
5. Has the pt yet achieved CR1?			<i>If Yes: Date (yyymmdd)</i>

- **Note 1.** *If points 1-5 are filled in and the pt has reached CR, sign and proceed to the INCLUSION section.*
- **Note 2.** *If the pt is not yet in CR, fill in points 1-5, sign and send to the National Study Office (NSO) for registration. The INCLUSION section should be completed, signed and sent when the pt has achieved CR.*

..... Date (yyymmdd) Signature (Investigator) Printed name				
Confirmation (NSO)						
Patient <i>registered</i> for the study?	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td></td> <td></td> </tr> </table>	Yes	No			Assigned UIN.....
Yes	No					

..... Date Signature (NSO) Printed name
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INCLUSION (*see page 2 for guidance*)

	Yes	No	Dates & Comments
6. Date of CR1 (<i>if not previously provided</i>)			<i>If Yes: Date (yyymmdd). If No: Comment:</i>
7. Incl. & Excl. criteria checked and approved			<i>If No: Comment:</i>
<i>If pt has at least one potential sibling donor</i>			
8. Sib donor HLA typing initiated?			<i>If Yes: Date (yyymmdd)</i>
<i>If pt has no potential sibling donor</i>			
9. Search for a MUD initiated?			<i>If Yes: Date (yyymmdd)</i>

..... Date Signature (Investigator) Printed name
<i>Sign and send to National Study Office (NSO).</i>		

CONFIRMATION (NSO)

10. Patient <i>included</i> ?	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td></td> <td></td> </tr> </table>	Yes	No			Inclusion date (<i>see page 2</i>)
Yes	No					
..... Date (yyymmdd) Signature (NSO) Printed name				

Comments on the Registration and Inclusion Form (RIF)

IMPORTANT

- I. HLA-typing of the patient can be performed at any point, e.g. at diagnosis.
- II. *Initiation of donor search* is by definition either blood sampling of a potential sib donor, or sending a request for a MUD search.
- III. The RIF should be sent to the NSO¹ in immediate connection with the initiation of donor search, preferably the same day.
- IV. If the investigator wants to initiate donor search before CR1 – fill in and send the Registration section. Fill in the Inclusion section when the pt achieves CR, or if she/he for any reason becomes not eligible for the study (e.g. no CR, early death). The “Dates & Comments” can be used for details. The NSO will request missing or not complete RIFs.
- V. The RIF can be sent by fax or e-mail (pdf format).

Guidance; paragraphs below refer to page 1

REGISTRATION DATA

1. Pts with good risk features should not be registered.
2. Pts should be deemed fit for RIC or standard consolidation chemotherapy.
3. Written informed consent should be obtained before registration.
4. This paragraph refers to
 - patients with potential sibling donor(s). Fill in **YES** box if the intention is to proceed with a MUD search in case potential sibling donor(s) are not HLA-identical or otherwise not eligible. Fill in **NO** box if there is no intention to proceed with a MUD search. (*If in doubt, the investigator is recommended to delay registration*).
 - patients without potential sibling donors. Fill in **YES** box.
5. Provide date if the pt has achieved CR1. Otherwise check NO box. Proceed according to point IV above.

INCLUSION DATA.

6. Provide CR1 date if not recorded in Registration section.
7. Check Inclusion and Exclusion criteria, see Protocol.
8. Provide date of blood sampling for HLA typing of the first potential sibling donor.
9. Provide date of dispatching a search request for a MUD.
10. “Inclusion date” (to be filled in by the NSO) is:
 - for pts registered and included in CR, the date from either point 8 or 9
 - for pts who were registered before CR, the date from point 6

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¹ NSO is the National Study Office