Data request

Centres should include all consecutive eligible patients over a 5 year period, **between 31 July 2009 and 31 July 2014**.

The patient registration form only collects the **Off-Label Transplant Use indication** and patient identification items. EBMT expects your MED A data forms to be registered at day 100 after transplant as usual.

Ethical Committee & Informed Consent

For the patients transplanted and registered prospectively with the EBMT, in general no ethical approval is necessary. However, regulations on approval may differ per centre. Please contact your Ethics Committee in case of any doubts.

It is sufficient to collect the general patient consent forms for data submission to the EBMT registry.

For more information, see the EBMT website: **www.ebmt.org**.

How to participate

If you would like to participate in this study, we kindly ask you to fill out the **centre registration form** and send it to the EBMT Data Office Leiden by fax or e-mail:

Registration and Data Management

Annelies Kleijne

E-mail: plerolebmt@lumc.nl

Telephone: +31 (0)71 526 4746
Fax: +49 711 4900 8723

EBMT Data Office Leiden
Dept. of Medical Statistics & Bio Informatics
LUMC, Postal zone S-05-P
PO BOX 9600,
2300 RC Leiden
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For clinical questions only, please contact the Investigators

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genzyme

The Chronic Leukemia Working Party
Chair: Theo de Witte

The Lymphoma Working Party
Chair: Peter Dreger

Plerixafor Off-Label Transplant Use

Plerixafor Off-Label Transplant Use

Introduction

A marketing authorisation for the use of plerixafor in the European Union (EU) was obtained on 31 July 2009.

The EMA license for plerixafor requires Genzyme to perform the outcome monitoring of patients transplanted with plerixafor-mobilised cells, compared to equivalent patients transplanted without the use of plerixafor. The EMA acceded the collaboration of Genzyme with EBMT to collect the required data by using the EBMT registry.

For this purpose Genzyme and the EBMT have developed the CALM study (Collaboration to collect Autologous transplant outcomes in Lymphoma and Myeloma).

As a post-marketing commitment to the EMA, Genzyme will additionally monitor the **off-label transplant use of plerixafor** using data in the EBMT registry.

Plerixafor Label Indication

Plerixafor is indicated in combination with G-CSF to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma whose cells mobilise poorly.

The Off-Label Transplant Use Study

The use of plerixafor in off-label settings will be collected from data entries over a 5-year period after the date of marketing authorization, namely data entered

between **31 July 2009 and 31 July 2014**.

It concerns patients treated with plerixafor, who meet **one or more of the following conditions**:

- Background disease other than Lymphoma or MM
- May be younger than 18 years of age
- Received transplant using ex-vivo plerixafor-mobilised cells
- Received treatment with plerixafor alone
- Contraindication for G-CSF
- Transplants using plerixafor-mobilised cells from allogeneic donor
- Received transplant using plerixafor-mobilised BM cells
- Routes of administration other than subcutaneous
- Patients whose cells do **not** mobilise poorly
- Other