
Cell Therapy MED-A FORM

Minimum essential data for the Cell Therapy Registry (CTR)

NOTE

The Cell Therapy Registry (CTR) aims to collect data on fetal or adult stem cells, or progenitor cells used for treatment other than haematopoietic stem cell transplantation or donor lymphocyte infusion, as well as data on the clinical characteristics and outcome of the patients. Data will be collected on characteristics of the cell graft, /in/ or /ex vivo/ cell manipulation and the cell origin (autologous versus allogeneic). Data will include details on patients treated with mesenchymal cells, for instance, to enhance haematopoietic engraftment, for prophylaxis and treatment of GvHD. The registry will also include data on patients treated by other disciplines for neurologic, rheumatologic, cardiac and inflammatory bowel diseases and tissue regeneration. For further information, please contact:

Dr. Katarina Le Blanc
Karolinska University Hospital
Centre for Allogeneic Stem Cell Transplantation
Huddinge
SE-141 86 Stockholm
Sweden
e-mail : Katarina.Leb Blanc@ki.se

How to submit data

Please follow the usual EBMT data flow to submit your CTR form. If you do not use ProMISe, and your centre belongs to a National Registry, please send the form to your national registry if listed in the Appendix of the [Data Submission Instructions](#).

Centres without a national registry can send the completed form to the EBMT Data Office:

Virginie Chesnel
EBMT Data Office
Faculté de Médecine St-Antoine
27, rue Chaligny
75571 Paris Cedex 12
France
Tel : +33.1.40.46.95.07
Fax : +33.1.40.46.96.07
e-mail : virginie.chesnel@upmc.fr

Alternatively, if you are a ProMISe user, you can enter the data yourself, using your access to the EBMT database.

Data Entry Instructions

If the indication is **Primary disease**, create a new form and in the first field "Form about to be entered", select code 9. The navigation should follow the CTR form order. (Note: please log in to any session other than a MED-B disease- specific reduced session to access the items contained in this form).

If the indication is **HSCT related**, the HSCT for the patient should be registered first. Once registered, load that patient into the Editor and change the code in "Form about to be entered" to code 9. The navigation should follow the CTR form order and will skip questions already answered in the HSCT registration, such as team, diagnosis – unless they are different for the CTR, in which case you will be given the option of entering the new details. If the patient has been referred from another centre, please request access in the usual way using the form: [patients given an HSCT in another centre](#)

If you have any queries or the navigation does not follow the order expected, please contact the EBMT-ProMISe helpdesk: registryhelpdesk@kcl.ac.uk. Please attach a screen capture of any errors using [Print Screen] on your keyboard, [Ctrl-C] to copy. Open Word and paste [Ctrl-V] the screen.

Cell Therapy Registry – Med-A

First report – 6 months after cell therapy

PRIMARY INDICATION: Primary disease HSCT related

CENTRE IDENTIFICATION

EBMT Code (CIC):
Hospital: Unit:
Contact person.....
Phone:.....
Fax:.....
e-mail:

REPORT INFORMATION

Date of this Report: - -
yyyy mm dd

PATIENT IDENTIFICATION

Unique Patient Number or Code
Compulsory, registrations will not be accepted without this item
Initials: (first name(s) _family name(s))
Date of Birth - -
yyyy mm dd
Sex Male Female

INDICATION FOR TREATMENT

If Primary disease:
Date of diagnosis - -
yyyy mm dd
 Autoimmune disease, specify
 Neurologic disorder, specify
 Heart disease, specify
 Haematologic, specify
 Other, specify
If Haematopoietic stem cell transplant related GvHD prophylaxis
 GvHD treatment
 Prevention of rejection
 Graft enhancement
 Bone marrow failure

CELL THERAPY TREATMENT

Date of first cell infusion - -
yyyy mm dd
Performance score System Karnofsky
Score: Lansky
10 20 30 40 50 60 70 80 90 100
Status at therapy
 Chronic Acute
 Acute exacerbation of chronic disease
Cell origin
 Allogeneic Autologous
Tissue cell source (check all that apply)
 Bone Marrow Peripheral Blood
 Cord Blood Adipose
 Endothelial cell progenitor
 Other, specify
Cell characteristic (check all that apply)
 Mononuclear cells CD34+
 Mesenchymal Unseparated bone marrow
 Other, specify

Chronological no. of cell therapy for this patient (if more than 6 months apart)

GRAFT MANIPULATION

Ex-vivo manipulation

No Yes: Growth factor, specify
 Other
 Expansion
 Unknown

In-vivo manipulation

In the donor
 No Yes: Growth factor, specify
 Other
 Unknown
In the patient
 No Yes: Growth factor, specify
 Other
 Unknown

TREATMENT

Route of infusion (check all that apply)

Intravenous
 Locally intra-arterially, specify artery
 Locally into tissue Intraperitoneally
 Intra bone Intrathecal
 Other route

Dose

Total N° of infusions
N° of cells infused per infusion x 10⁶/kg

Associated procedure (ie: HSCT CABG, decompression of spinal cord injury, matrix implant etc.)

No
 Yes: specify
 Prior to cell therapy
 Simultaneous
 Post cell therapy
 Unknown

RESPONSE

Best clinical/biological response after cell therapy

Complete sustained remission (CR)
 Partial sustained remission (PR)
 Remission (CR or PR) followed by relapse or progression
 Stable Progression Unknown

Laboratory response (if applicable)

Normalized
 Improvement
 Unchanged
 Worsening

Specify laboratory parameter

DATE OF LAST CONTACT

Date of last follow up or death: - -
yyyy mm dd

Survival Status

Alive Dead
 Check here if patient lost to follow up

Main Cause of Death (check only one main cause)

Relapse or Progression (if indication: primary disease)
 HSCT related (if applicable):
 Cell Therapy related:
 Other
 Unknown

