

# ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Initials:

Today's Date:

Infusion Date:

CIBMTR Center Number:

## Form 4000 R5.0: Cellular Therapy Essential Data Pre-Infusion Form

Center: \_\_\_\_\_

CRID: \_\_\_\_\_

### Key Fields

Sequence Number: \_\_\_\_\_

Date Received: \_\_\_\_-\_\_\_\_-\_\_\_\_

CIBMTR Center Number: \_\_\_\_\_

CIBMTR Research ID: \_\_\_\_\_

Event date: \_\_\_\_-\_\_\_\_-\_\_\_\_

### Recipient Data

Questions: 1 - 13

**This form must be completed for all recipients of non-HCT cellular products. For recipients of hematopoietic cell transplants, complete a form 2400 - Pre-Transplant Essential Data.**

**This form reflects baseline recipient data for one course of cellular therapy.**

#### 1 Ethnicity

- Hispanic or Latino
- Not Hispanic or Latino
- Not applicable (not a resident of the USA)
- Unknown

#### 2 Race (check all that apply)

- White
- Black or African American
- Asian
- American Indian or Alaska Native
- Native Hawaiian or Other Pacific Islander
- Not reported
- Unknown

#### 3 Has the recipient signed an IRB / Ethics Committee-approved consent form for submitting research data to the CIBMTR?

- Yes (patient consented)
- No (patient declined)
- Not approached
- Not applicable

4 Date form was signed: \_\_\_\_-\_\_\_\_-\_\_\_\_

#### 5 Is the recipient participating in a cellular therapy clinical trial?

- yes  no

### Clinical Trials (1)

Questions: 6 - 11

#### 6 Study sponsor

- BMT CTN
- RCI BMT
- USIDNET
- COG
- Corporate / Industry
- EudraCT
- UMIN
- Investigator initiated
- Other

7 Specify corporate / industry sponsor name: \_\_\_\_\_

8 Specify EudraCT number: \_\_\_\_\_

9 Specify UMIN number: \_\_\_\_\_

10 Specify other sponsor: \_\_\_\_\_

11 Specify the ClinicalTrials.gov identification number: \_\_\_\_\_

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12 Is the recipient receiving cellular therapy outside the context of a clinical trial?

- Yes  No

13 Specify the reason for not being on a clinical trial (check all that apply)

- Institutional guidelines / standard treatment  
 Hospital exemption  
 Compassionate use

### Cellular Therapy and HCT History

Questions: 14 - 28

14 Is this the first application of cellular therapy (non-HCT)?

- Yes  
 No (recipient has previously been treated using cellular therapy)  
 Unknown

15 Were all prior cellular therapies (non-HCT) reported to the CIBMTR?

- Yes  No  Unknown

16 Specify the number of prior cellular therapies: \_\_\_\_\_

### Prior Cellular Therapies (1)

Questions: 17 - 22

17 Date of the prior cellular therapy: \_\_\_\_ - \_\_\_\_ - \_\_\_\_  Date estimated

18 Was the cellular therapy performed at a different institution?

- Yes  No

**Specify the institution that performed the prior cellular therapy:**

19 Name: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Country: \_\_\_\_\_

20 Specify the indication for the prior cellular therapy

- Promote stem cell engraftment (e.g. co-infusion with HCT)
- Suboptimal donor chimerism (post-HCT)
- Immune reconstitution (post-HCT)
- GVHD prophylaxis (with HCT)
- GVHD treatment (post-HCT)
- Prevent disease relapse (post-HCT)
- Relapsed, persistent or progressive disease (post-HCT)
- Infection treatment
- Infection prophylaxis
- B cell lymphoproliferative disorder (PTLD, EBV lymphoma)
- Autoimmune disease
- Cardiovascular disease
- Musculoskeletal disorder
- Neurologic disease
- Ocular disease
- Pulmonary disease
- Solid tumor
- Malignant hematologic disorder
- Non-malignant disorder
- Unknown
- Other indication

21 Specify other indication: \_\_\_\_\_

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**34** What is the tissue source of the cellular product? (check all that apply)

- Bone marrow
- Cord blood unit
- Peripheral blood
- Adipose tissue
- Amniotic fluid
- Cardiac tissue
- Hepatic tissue
- Neuronal tissue
- Ophthalmic tissue
- Pancreatic tissue
- Placenta
- Tumor
- Umbilical cord
- Other tissue source
- Unknown

**35** Specify other tissue source: \_\_\_\_\_

**36** What is the cell type? (Check all that apply)

- Lymphocytes (unselected)
- CD4+ lymphocytes
- CD8+ lymphocytes
- Cytotoxic T lymphocytes (CTLs)
- Natural killer cells (NK cells)
- Dendritic cells / tumor cell hybridomas (tumor vaccines)
- Mesenchymal stromal stem cells (MSCs)
- Unspecified mononuclear cells
- Endothelial progenitor cells
- Human umbilical cord perivascular (HUCPV) cells
- Cardiac progenitor cells
- Islet cells
- Oligodendrocytes
- Other cell type

**37** Specify other cell type: \_\_\_\_\_

**38** Where was the cellular therapy product manufactured / processed?

- Pharmaceutical / biotech company
- Cell processing laboratory off site
- Cell processing laboratory at the same center as the product is being infused
- Other site

**39** Specify other site: \_\_\_\_\_

**40** Specify pharmaceutical / biotech company

- Atara Biotherapeutics
- Bellicum Pharmaceuticals
- Bluebird Bio
- Celgene
- Juno Therapeutics
- Kite Pharma
- Mesoblast
- Novartis
- Other pharmaceutical company

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CRID: \_\_\_\_\_

### Specify the institution / company where the cellular product was manufactured:

41 Name: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Country: \_\_\_\_\_

#### 42 Name of product

- Tisagenlecleucel (Kymriah®)
- Axicabtagene Ciloleucel (Yescarta®)
- Other product

43 Specify other product: \_\_\_\_\_

### Planned HCT

44 Is a subsequent HCT part of the overall treatment protocol?

- Yes  No

45 Specify the HCT type

- Autologous  Allogeneic

46 Specify the circumstances in which the subsequent HCT will be performed

- Regardless of response to cellular therapy
- Only if the patient responds to cellular therapy
- Only if the patient fails to respond or has an incomplete response

### Indication for Cellular Therapy

Questions: 47 - 60

47 Is the cellular therapy being given for prevention?

- Yes  No

48 Reason for prevention

- GVHD prophylaxis (with HCT)
- Prevent disease relapse (post-HCT)
- Infection prophylaxis

49 Indication for cellular therapy

- Suboptimal donor chimerism (Post-HCT)
- Immune reconstitution (Post-HCT)
- GVHD treatment (Post-HCT)
- Malignant hematologic disorder - **Also complete CIBMTR Form 2402**
- Non-malignant disorder - **Also complete CIBMTR Form 2402**
- Solid tumor - **Also complete CIBMTR Form 2402**
- Cardiovascular disease
- Musculoskeletal disease
- Neurologic disease
- Ocular disease
- Pulmonary disease
- Infection treatment
- Other indication

50 Date of diagnosis: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

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### Cardiovascular disease

51 Specify cardiovascular disease

- AMI, acute myocardial infarction (701)
- Chronic coronary artery disease (ischemic, cardiomyopathy) (702)
- Heart failure (non-ischemic etiology) (703)
- Other cardiovascular disease (709)
- Limb ischemia (710)
- Thromboangitis obliterans (711)
- Other peripheral vascular disease (719)

52 Specify other cardiovascular disease: \_\_\_\_\_

53 Specify other peripheral vascular disease: \_\_\_\_\_

### Musculoskeletal

54 Specify musculoskeletal disorder

- Avascular necrosis of femoral head (721)
- Osteoarthritis (722)
- Osteogenesis imperfecta (723)
- Traumatic joint injury (724)
- Other musculoskeletal disorder (729)

55 Specify other musculoskeletal disorder: \_\_\_\_\_

### Neurologic Disease

56 Specify neurologic disease

- Acute cerebral vascular ischemia (731)
- ALS, amyotrophic lateral sclerosis (732)
- Parkinson disease (733)
- Spinal cord injury (734)
- Cerebral palsy (753)
- Congenital hydrocephalus (754)
- Myasthenia gravis (601)
- Duchenne muscular dystrophy (735)
- Other neurologic disease (749)

57 Specify other neurologic disease: \_\_\_\_\_

### Ocular

58 Specify ocular disease: \_\_\_\_\_

### Pulmonary

59 Specify pulmonary disease: \_\_\_\_\_

### Other

60 Specify other indication: \_\_\_\_\_

## Infection

Questions: 61 - 67

Specify organism code(s):

- 61 \_\_\_\_\_
- 62 \_\_\_\_\_
- 63 \_\_\_\_\_
- 64 \_\_\_\_\_
- 65 \_\_\_\_\_
- 66 \_\_\_\_\_

67 Specify other organism: \_\_\_\_\_

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CRID: \_\_\_\_\_

### Disease Assessment at Last Evaluation Prior to Cellular Therapy

Questions: 68 - 93

**Specify the method(s) of disease detection below. For each method used, if the result was positive report the first date the disease was detected; if the result was negative report the last date the method was used prior to cellular therapy.**

**68** Was the disease assessed prior to the cellular therapy?

Yes  No

**69** Was the disease status assessed by molecular testing? (e.g. PCR)

Yes  No  Not Applicable

**70** Date sample collected: \_\_\_\_-\_\_\_\_-\_\_\_\_

**71** Was disease detected?

yes  no

**72** Was the status considered a disease relapse or progression?

yes  no

**73** Was the disease status assessed via flow cytometry? (immunophenotyping)

Yes  No  Not Applicable

**74** Date sample collected: \_\_\_\_-\_\_\_\_-\_\_\_\_

**75** Was disease detected?

yes  no

**76** Was the status considered a disease relapse or progression?

yes  no

**77** Was the disease status assessed by cytogenetic testing? (karyotyping or FISH)

Yes  No  Not Applicable

**78** Was the disease status assessed via karyotyping?

Yes  No  Not Applicable

**79** Date sample collected: \_\_\_\_-\_\_\_\_-\_\_\_\_

**80** Was disease detected?

yes  no

**81** Was the status considered a disease relapse or progression?

yes  no

**82** Was the disease status assessed via FISH?

Yes  No  Not Applicable

**83** Date sample collected: \_\_\_\_-\_\_\_\_-\_\_\_\_

**84** Was disease detected?

yes  no

**85** Was the status considered a disease relapse or progression?

yes  no

**86** Was the disease status assessed by radiological assessment? (e.g. PET, MRI, CT)

Yes  No  Not Applicable

**87** Date assessed: \_\_\_\_-\_\_\_\_-\_\_\_\_

**88** Was disease detected?

yes  no

**89** Was the disease status assessed by clinical / hematologic assessment?

yes  no

**90** Date assessed: \_\_\_\_-\_\_\_\_-\_\_\_\_

**91** Was disease detected?

yes  no

**92** What was the recipient's disease status immediately prior to the cellular therapy?

Complete remission (CR)

Not in complete remission

**93** Date assessed: \_\_\_\_-\_\_\_\_-\_\_\_\_

### Systemic Therapy Prior to Cellular Therapy

Questions: 94 - 249

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<input type="text"/> <input type="text"/> <input type="text"/> 20 <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> 20 <input type="text"/>	<input type="text"/>
Month Day Year	Month Day Year	

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Center:

CRID:

206 Specify other mAb: \_\_\_\_\_

207 Total dose: \_\_\_\_\_ mg

208 Date started: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**209 Nitrosourea**

Yes  No

**210 Carmustine (BCNU, Gliadel)**

yes  no

211 Total dose: \_\_\_\_\_ mg

212 Date started: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**213 CCNU (Lomustine)**

Yes  No

214 Total dose: \_\_\_\_\_ mg

215 Date started: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**216 Other nitrosourea**

Yes  No

217 Specify other nitrosourea: \_\_\_\_\_

218 Total dose: \_\_\_\_\_ mg

219 Date started: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**220 Paclitaxel (Taxol, Xyotax)**

Yes  No

221 Total dose: \_\_\_\_\_ mg

222 Date started: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**223 Teniposide (VM26)**

yes  no

224 Total dose: \_\_\_\_\_ mg

225 Date started: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**226 Thiotepa**

Yes  No

227 Total dose: \_\_\_\_\_ mg

228 Date started: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**229 Treosulfan**

Yes  No

230 Total dose: \_\_\_\_\_ mg

231 Date started: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**232 Tyrosine kinase inhibitors (TKI)**

yes  no

**233 Dasatinib (Sprycel)**

yes  no

234 Total dose: \_\_\_\_\_ mg

235 Date started: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**236 Imatinib mesylate (STI571, Gleevec)**

yes  no

237 Total dose: \_\_\_\_\_ mg

238 Date started: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**239 Nilotinib (AMN107, Tasigna)**

yes  no

240 Total dose: \_\_\_\_\_ mg

241 Date started: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**242 Other tyrosine kinase inhibitor**

Yes  No

243 Specify other tyrosine kinase inhibitor: \_\_\_\_\_

244 Total dose: \_\_\_\_\_ mg

245 Date started: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**246 Other drug**

Yes  No

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CRID: \_\_\_\_\_

247 Specify other drug: \_\_\_\_\_

248 Total dose: \_\_\_\_\_ mg

249 Date started: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

### Functional Status

Questions: 250 - 252

Specify the functional status of the recipient immediately prior to the cellular therapy:

250 What scale was used to determine the recipient's functional status prior to the cellular therapy

- Karnofsky (recipient age ≥ 16 years)  
 Lansky (recipient age ≥ 1 and < 16 years)

251 Karnofsky Scale (recipient age ≥ 16 years) \_\_\_\_\_

252 Lansky Scale (recipient age ≥ 1 and < 16 years) \_\_\_\_\_

### Comorbid Conditions

Questions: 253 - 311

This section to be completed for malignant hematologic disorders and solid tumor indications.

253 Were there clinically significant co-existing diseases or organ impairment at time of patient assessment prior to preparative regimen? Source: Blood, 2005 Oct 15;106(8):2912-2919

- yes  no

254 Arrhythmia - For example, any history of atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias requiring treatment

- yes  no  Unknown

255 Cardiac - Any history of coronary artery disease (one or more vessel-coronary artery stenosis requiring medical treatment, stent, or bypass graft), congestive heart failure, myocardial infarction, OR ejection fraction ≤ 50% on the most recent test

- yes  no  Unknown

256 Cerebrovascular disease - Any history of transient ischemic attack, subarachnoid hemorrhage or cerebrovascular accident

- yes  no  Unknown

257 Diabetes - Requiring treatment with insulin or oral hypoglycemics in the last 4 weeks but not diet alone

- yes  no  Unknown

258 Heart valve disease - Except asymptomatic mitral valve prolapse

- yes  no  Unknown

259 Hepatic, mild - Chronic hepatitis, bilirubin > upper limit of normal to 1.5 × upper limit of normal, or AST/ALT > upper limit of normal to 2.5 × upper limit of normal at the time of transplant OR any history of hepatitis B or hepatitis C infection

- yes  no  Unknown

260 Hepatic, moderate / severe - Liver cirrhosis, bilirubin > 1.5 × upper limit of normal, or AST/ALT > 2.5 × upper limit of normal

- yes  no  Unknown

261 Infection - For example, documented infection, fever of unknown origin, or pulmonary nodules requiring continuation of antimicrobial treatment after day 0

- yes  no  Unknown

262 Inflammatory bowel disease - Any history of Crohn's disease or ulcerative colitis requiring treatment

- yes  no  Unknown

263 Obesity - Patients with a body mass index > 35 kg/m<sup>2</sup> prior to the start of conditioning

- yes  no  Unknown

264 Peptic ulcer - Any history of peptic ulcer confirmed by endoscopy and requiring treatment

- yes  no  Unknown

265 Psychiatric disturbance - For example, depression, anxiety, bipolar disorder or schizophrenia requiring psychiatric consult or treatment in the last 4 weeks

- yes  no  Unknown

266 Pulmonary, moderate - Corrected diffusion capacity of carbon monoxide and/or FEV<sub>1</sub> 66-80% or dyspnea on slight activity at transplant

- yes  no  Unknown

267 Pulmonary, severe - Corrected diffusion capacity of carbon monoxide and/or FEV<sub>1</sub> ≤ 65% or dyspnea at rest or requiring oxygen at transplant

- yes  no  Unknown

268 Renal, moderate / severe - Serum creatinine > 2 mg/dL or > 177 μmol/L or on dialysis at transplant, OR prior renal transplantation

- yes  no  Unknown

269 Rheumatologic - For example, any history of systemic lupus erythematosis, rheumatoid arthritis, polymyositis, mixed connective tissue disease, or polymyalgia rheumatica requiring treatment (do NOT include degenerative joint disease, osteoarthritis)

- yes  no  Unknown

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**270 Solid tumor, prior - Treated at any time point in the patient's past history, excluding non-melanoma skin cancer, leukemia, lymphoma or multiple myeloma**

yes  no  Unknown

**271 Breast cancer**

yes  no

**272 Year of diagnosis:** \_\_\_\_\_

**273 Central nervous system (CNS) malignancy (glioblastoma, astrocytoma)**

yes  no

**274 Year of diagnosis:** \_\_\_\_\_

**275 Gastrointestinal malignancy (colon, rectum, stomach, pancreas, intestine)**

yes  no

**276 Year of diagnosis:** \_\_\_\_\_

**277 Genitourinary malignancy (kidney, bladder, ovary, testicle, genitalia, uterus, cervix)**

yes  no

**278 Year of diagnosis:** \_\_\_\_\_

**279 Lung cancer**

yes  no

**280 Year of diagnosis:** \_\_\_\_\_

**281 Melanoma**

yes  no

**282 Year of diagnosis:** \_\_\_\_\_

**283 Oropharyngeal cancer (tongue, buccal mucosa)**

yes  no

**284 Year of diagnosis:** \_\_\_\_\_

**285 Sarcoma**

yes  no

**286 Year of diagnosis:** \_\_\_\_\_

**287 Thyroid cancer**

yes  no

**288 Year of diagnosis:** \_\_\_\_\_

**289 Other co-morbid condition**

yes  no  Unknown

**290 Specify other co-morbid condition:** \_\_\_\_\_

**291 Was there a history of malignancy (hematologic or non-melanoma skin cancer) other than the primary disease for which this infusion is being performed?**

yes  no

**Specify which malignancy(ies) occurred:**

**292 Acute myeloid leukemia (AML / ANLL)**

yes  no

**293 Year of diagnosis:** \_\_\_\_\_

**294 Other leukemia, including ALL**

yes  no

**295 Year of diagnosis:** \_\_\_\_\_

**296 Specify leukemia:** \_\_\_\_\_

**297 Clonal cytogenetic abnormality without leukemia or MDS**

yes  no

**298 Year of diagnosis:** \_\_\_\_\_

**299 Hodgkin disease**

yes  no

**300 Year of diagnosis:** \_\_\_\_\_

**301 Lymphoma or lymphoproliferative disease**

yes  no

**302 Year of diagnosis:** \_\_\_\_\_

**303 Was the tumor EBV positive?**

yes  no

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