# Part A: General Information

Provide the legal name and address of the institution or corporation responsible for the provision of transplant services.

**Name:**

**Name used when submitting data to CIBMTR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Street Address:**

**City:**

**State:**  **Zip**:

**Hospital Tax ID Number:**

Chief Executive Officer:

**Program Administrator Telephone: \_\_\_**

|  |  |  |
| --- | --- | --- |
| A-1. Is your institution affiliated with or the parent corporation of other hospitals/institutions? | Yes | No |

If yes, what is the name(s) of the affiliated institutions and the nature of the relationship?

**A-2. Are any pre- or post-cellular treatment episodes**

**(clinic visit, evaluation, major diagnostic testing, Y**es  No

**etc.) being provided at the affiliated institutions listed in**

**question A1?**

If yes, please list which affiliate and which type of service.

## A-3. Is your institution currently accredited by any of the following organizations without exception, condition or contingency:

|  |  |  |
| --- | --- | --- |
| **Accreditation Organization**  **(FACT accreditation is addressed in question A-4)** | **YES** | **NO** |
| The Joint Commission |  |  |
| National Integrated Accreditation of Healthcare Organizations (DNV-GL NIAHO) |  |  |
| Healthcare Facilities Accreditation Program (HFAP) |  |  |
| Center for Improvement in Healthcare Quality (CIHQ) |  |  |

**A-4. Current FACT Program Accreditation / Certification\***

FACT – Clinical Program

Adult Autologous Yes  No  or Yes  No

Adult Allogeneic Yes  No  or Yes  No

Pediatric Autologous Yes  No  or Yes  No

Pediatric Allogeneic Yes  No  or Yes  No

FACT – Collection Program Yes  No  or Yes  No

FACT – Cell Processing Program Yes  No  or Yes  No

FACT – Immune Effector Cell Program Yes  No  or Yes  No

\***NOTE:** ASTCT does notwarrant, guarantee, or endorse every accreditation/certification program listed above, and transplant centers need not obtain accreditation/certification from every program listed. Payers individually establish requirements for inclusion of transplant centers in their networks.

**A-5. Number of CAR-T administrations performed with FDA-approved products, by patient age**

Record the total number of administrations performed in the years indicated. Patients with multiple administrations will be counted more than once. Do not include Managed Access, Expanded Access and/or Individual IND administrations in this table.

| **Year** | **Age 0-10** | **Age 11-17** | **Age 18-64** | **Age 65+** |
| --- | --- | --- | --- | --- |
| **2018** |  |  |  |  |
| **2019** |  |  |  |  |
| **2020** |  |  |  |  |
| **2021** |  |  |  |  |
| **Total** |  |  |  |  |

**A-6. Number of CAR-T administrations performed with clinical trial or research protocol products, by patient age**

Record the total number of administrations performed in the years indicated. Patients with multiple administrations will be counted more than once. Include Managed Access, Expanded Access, and/or Individual IND administrations.

| **Year** | **Age 0-10** | **Age 11-17** | **Age 18-64** | **Age 65+** |
| --- | --- | --- | --- | --- |
| **2018** |  |  |  |  |
| **2019** |  |  |  |  |
| **2020** |  |  |  |  |
| **2021** |  |  |  |  |
| **Total** |  |  |  |  |

**A-7. Has the Program been closed or suspended for any reason during the past 36 months?**

Yes  No

If yes, provide dates and explain:

**A-8. How does the Program provide the following cell therapy-related services?**

Apheresis  inpatient  outpatient  both

Lympho-depleting Regimens  inpatient  outpatient  both

Cell Therapy Infusion  inpatient  outpatient  both

Recovery  inpatient  outpatient  both

**A-9** **Does the Program perform CAR-T cells followed by a planned allogeneic stem cell**

**transplant**? Yes  No

If yes, please provide additional information about these scenarios.

#### A-10. Indications for which FDA-approved CAR-T therapies are administered in the Program:

Acute lymphoblastic leukemia – adult

Acute lymphoblastic leukemia – pediatric

Diffuse large B-cell lymphoma/Primary mediastinal B-cell lymphoma/Transformed lymphoma

Follicular lymphoma

Mantle cell lymphoma

Multiple myeloma

#### A-11. Manufacturers with which the Program is currently (at the time of RFI completion) certified for FDA-approved CAR-T therapies:

Bristol Myers Squibb

J&J/Janssen/Legend

Kite Pharma/Gilead

Novartis

Other: \_\_\_\_\_\_\_\_\_

**Part B: Protocols**

**B-1. Are all patients managed under a protocol (either research, institutional standard of care or in a REMS program per a commercial source)?** Yes  No

**If treatments are performed “off protocol”, how is the decision made?**

**B-2.** **Does the Program report CAR-T data to the CIBMTR?** Yes  No

**Part C: Cellular Therapy Team**

| **Name** | **Board Certification / Specialty** | **Years of experience actively managing cellular therapy patients** |
| --- | --- | --- |
| **Adult Program Director:** |  |  |
|  |  |  |
| **Adult Treating Physician(s):** |  |  |
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| **Pediatric Program Director:** |  |  |
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|  |  |  |
| **Pediatric Treating Physician(s):** |  |  |
|  |  |  |
|  |  |  |
| **IECT Coordinator:** |  |  |
|  |  |  |
|  |  |  |

**Part D: Summary Information**

**D-1. Describe the Program’s unique qualities**.

**D-2. Provide any additional information that you feel is important regarding the Program**.

**D-3 Describe the support process in place regarding emergency care or hospitalizations for CAR-T related adverse events.**

I certify that the information contained in this survey and all attachments is accurate, complete, and true.

I understand that submission of this survey does not automatically result in participation or continued participation.

Name Signature

Title Date

Name Signature

Title Program Medical Director Date