# 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:**

Program Clinical Director Email:

**Program Administrator Director Email:**

|  |  |  |
| --- | --- | --- |
| 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 there cellular therapy-associated clinical services**

**(evaluation, major diagnostic testing, cell collection/apheresis,** Yes [ ]  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. 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-4. Number of CAR-T administrations performed with FDA-approved products, by patient age**

Record the total number of administrations performed in the years indicated. Note: Please INCLUDE FDA-approved products given via an Expanded Access/Managed Access Protocol. Do not include individual Investigational New Drug (IND) or other clinical trial administrations in this table.

| **Calendar Year** | **Age 0-10** | **Age 11-17** | **Age 18-64** | **Age 65+** |
| --- | --- | --- | --- | --- |
| **2021** |  |  |  |  |
| **2022** |  |  |  |  |
| **2023** |  |  |  |  |
| **2024** |  |  |  |  |
| **Total** |  |  |  |  |

**A-5. Number of CAR-T administrations performed with FDA-approved products, by product, 2021-2024 (through 9/30/2024)**

Record the total number of administrations performed in the years indicated. Note: Please INCLUDE FDA-approved products given via an Expanded Access/Managed Access Protocol. Do not include individual Investigational New Drug (IND) or other clinical trial administrations in this table.

|  | **Total** | **90-day survival** |
| --- | --- | --- |
| **Product** | **# patients infused** | **# patients**  | **%** |
| **Idecabtagene Vicleucel** |  |  |  |
| **Obecabtagene Autoleucel** |  |  |  |
| **Lisocabtagene Maraleucel** |  |  |  |
| **Ciltacabtagene Autoleucel** |  |  |  |
| **Tisagenleclucel** |  |  |  |
| **Brexucabtagene Autoleucel** |  |  |  |
| **Axicabtagene Ciloleucel** |  |  |  |
| **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 administration events will be counted more than once, multiple administrations within one event (i.e. split dosing) will be counted once. Include Individual IND administrations.

| **Calendar****Year** | **Age 0-10** | **Age 11-17** | **Age 18-64** | **Age 65+** |
| --- | --- | --- | --- | --- |
| **2021** |  |  |  |  |
| **2022** |  |  |  |  |
| **2023** |  |  |  |  |
| **2024** |  |  |  |  |
| **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

Lymphodepleting Regimens [ ]  inpatient [ ]  outpatient [ ]  both

Cell Therapy Infusion [ ]  inpatient [ ]  outpatient [ ]  both

Post-infusion Care [ ]  inpatient [ ]  outpatient [ ]  both

**A-9.** 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-10. 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

[ ]  Autolus

[ ]  Other: \_\_\_\_\_\_\_\_\_

**Part B: Protocols**

**B-1. Are all patients managed under a protocol (either research or institutional standard of care)?** 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** | **Became a member of this team****Month/Year** |
| --- | --- | --- | --- |
| **Adult Program Clinical Director:** |  |  |  |
|  |  |  |  |
| **Adult Program Administrative Director:** |  |  |  |
|  |  |  |  |
| **Adult Treating Physician(s):** |  |  |  |
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| **Pediatric Program Clinical Director:** |  |  |  |
|  |  |  |  |
| **Pediatric Program Administrative Director:** |  |  |  |
|  |  |  |  |
| **Pediatric Treating Physician(s):** |  |  |  |
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|  |  |  |  |
| **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**.

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 Program Administrative Director Date

Name Signature

Title Program Clinical Director Date