# 4/18/2023

# 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. 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+** |
| --- | --- | --- | --- | --- |
| **2019** |  |  |  |  |
| **2020** |  |  |  |  |
| **2021** |  |  |  |  |
| **2022** |  |  |  |  |
| **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 Individual IND administrations.

| **Calendar****Year** | **Age 0-10** | **Age 11-17** | **Age 18-64** | **Age 65+** |
| --- | --- | --- | --- | --- |
| **2019** |  |  |  |  |
| **2020** |  |  |  |  |
| **2021** |  |  |  |  |
| **2022** |  |  |  |  |
| **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:** |  |  |
|  |  |  |
|  |  |  |
| **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