

ASTCT Cellular Therapy RFI 2026: Program Information

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Part A: General Program Information

Provide the legal name and address of the institution or corporation responsible for the provision of Chimeric Antigen Receptor T-Cell Therapy (CAR-T) and Cellular Gene Therapy (CGT) services.

Institution 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:

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?

Are there cellular therapy-associated clinical services (evaluation, major diagnostic testing, cell collection/apheresis, etc.) being provided at the affiliated institutions listed in the question above?

Yes No

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

Does the Program report CAR-T data to the CIBMTR?

Yes No

If yes, the *Data for RFI* feature located in the CIBMTR portal may be used to extract data for some of the tables below. Look for the “CIBMTR Data for RFI” link in the instructions for each section. Please note that all data should be internally verified prior to submission to confirm accuracy and completeness.

Current Program Accreditations/Certifications:

FACT – Clinical Program

Adult Autologous Yes No

Adult Allogeneic Yes No

Pediatric Autologous Yes No

Pediatric Allogeneic Yes No

FACT – Collection Program Yes No

FACT – Cell Processing Program Yes No

FACT – Immune Effector Cell Program Yes No

Cell Therapy Laboratory

CAP Yes No

CLIA Yes No

AABB Yes No

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

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Part B: Chimeric Antigen Receptor T-Cell Therapy Program Information

This section references CAR-T treatments only.

B-1. How does the Program provide the following cell therapy-related services?

Apheresis	<input type="checkbox"/> inpatient	<input type="checkbox"/> outpatient	<input type="checkbox"/> both
Lymphodepleting Regimens	<input type="checkbox"/> inpatient	<input type="checkbox"/> outpatient	<input type="checkbox"/> both
Cell Therapy Infusion	<input type="checkbox"/> inpatient	<input type="checkbox"/> outpatient	<input type="checkbox"/> both
Acute Post-infusion Care	<input type="checkbox"/> inpatient	<input type="checkbox"/> outpatient	<input type="checkbox"/> both

B-3. Is a third-party vendor used for cell processing or apheresis services? Yes No

If so, for which services:

B-4. Products the Program currently (at the time of RFI completion) offers:

- Idecabtagene Vicleucel
- Obecabtagene Autoleucel
- Lisocabtagene Maraleucel
- Ciltacabtagene Autoleucel
- Tisagenleclucel
- Brexucabtagene Autoleucel
- Axicabtagene Ciloleucel

B-5. Number of CAR-T administration events performed with FDA-approved products, by patient age *Administration event is when a complete dose of an FDA-approved product being administered (i.e. count a split administration once, count each reinfusion episode separately) Do not include individual Investigational New Drug (IND) or other clinical trial administrations in this table.*

* CIBMTR Data for RFI

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

B-6. Number of CAR-T administrations performed with FDA-approved products, by product, calendar years 2020-2024 (through 12/31/2024)

Record the total number of administrations performed between calendar years 2020-2024. Administration event is when a complete dose of an FDA-approved product being administered (i.e. count a split administration once, count each reinfusion episode separately) Do not include individual Investigational New Drug (IND) or other clinical trial administrations in this table.

* CIBMTR Data for RFI

Product	Total	100-day survival	
	# patients infused	# patients	%
Idecabtagene Vicleucel			
Obecabtagene Autoleucel			
Lisocabtagene Maraleucel			
Ciltacabtagene Autoleucel			
Tisagenleclucel			
Brexucabtagene Autoleucel			
Axicabtagene Ciloleucel			

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B-7. Number of CAR-T administrations performed with clinical trial or research protocol products, by patient age

Count administration events when a complete dose is administered (i.e. count a split administration once, count each reinfusion episode separately)

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

Part C: Cellular Gene Therapy (CGT) Program Information

C-1. Products the Program currently (at the time of RFI completion) offers:

- Donislecel (Lantidra)
- Atidarsagene autotemcel (Lenmeldy)
- Lovotibeglogene autotemcel (Lyfgenia)
- Omidubicel-onlv (Omisirge)
- Allogenic processed thymus tissue-agdc (Rethymic)
- Remestemcel-L-rknd (Ryoncil)
- Elivaldogene autotemcel (Skysona)
- Betibeglogene autotemcel (Zynteglo)
- Prademagene zamikeracel (Zevaskyn)
- Exagamglogene autotemcel (Casgvey) - SCD
- Exagamglogene autotemcel (Casgvey) – Thal

C-2. Number of CGT administrations performed with FDA-approved products, by product, during calendar years 2024-2025 (through 12/31/2025)

Record the total number of administrations performed between calendar years 2024-2025. Administration event is when a complete dose of an FDA-approved product being administered (i.e. count a split administration once, count each reinfusion episode separately) Do not include individual Investigational New Drug (IND) or other clinical trial administrations in this table.

Product Name	2024	2025
Donislecel (Lantidra)		
Atidarsagene autotemcel (Lenmeldy)		
Lovotibeglogene autotemcel (Lyfgenia)		
Omidubicel-onlv (Omisirge)		
Allogenic processed thymus tissue-agdc (Rethymic)		
Remestemcel-L-rknd (Ryoncil)		
Elivaldogene autotemcel (Skysona)		
Betibeglogene autotemcel (Zynteglo)		
Prademagene zamikeracel (Zevaskyn)		
Exagamglogene autotemcel (Casgvey) - SCD		
Exagamglogene autotemcel (Casgvey) – thal		

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Part D: Quality Program, Clinical Trials, and Patient Support Information

D-1.

Has the Program been closed or suspended for any reason during the past 36 months?

Yes No

If yes, provide dates and explain:

Have there been any changes in medical leadership of the Adult Program in the past 12 months?

Yes No

Have there been any changes in medical leadership of the Pediatric Program in the past 12 months?

Yes No

If yes, provide date(s) and explain:

D-2. Patient Selection

Describe the patient selection processes utilized by the Program (patient selection committee, frequency with which it meets, who attends, are minutes taken, etc).

Describe protocols for patient selection, including indications and contraindications for adult and pediatric autologous and allogeneic transplantation. Include the match criteria for allogeneic transplants.

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?

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D-3. Please list all open and enrolling Cellular Gene Therapy & CAR-T clinical trials your institution offers:
Provide the trial name, NCD number and clinicaltrials.gov page for all interventional treatment trials that were open to accrual during this RFI cycle, calendar year 2025. (attach separate file if needed)

Trial Name	NCT Number	Clinicaltrials.gov Link

D-4. Describe the Program’s approach to supporting patient access, and quality clinical and psychosocial care. For example, describe local lodging support, care coordination approaches, and key components of your FACT quality management plan. (attach separate file if needed)

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Part 4: Attestation

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 _____