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# Current use and outcomes of cellular therapy: Brazilian Summary Slides – 2026

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## ABSTRACT

**Objective:** To describe CAR-T cell therapy activity and outcomes reported by Brazilian centers participating in the Brazilian Society of Cellular Therapy and Bone Marrow Transplantation (SBTMO)/Center for International Blood and Marrow Transplant Research (CIBMTR) network between January 2020 and December 2025. **Methods:** Data from patients who received commercial or academic CAR-T cell therapies in Brazilian centers were extracted from the CIBMTR database. Participating centers reported data through the FormsNet3 platform, allowing standardized collection of patient, disease, and treatment-related variables. Descriptive analyses were performed, and overall survival (OS) was estimated using the Kaplan–Meier method. **Results:** A total of 219 CAR-T cell infusions were reported. The median age was 57 years (range, 4–83 years). The most common indications were non-Hodgkin lymphoma (NHL) (146 patients, 67%), multiple myeloma (MM) (39 patients, 18%), acute lymphoblastic leukemia (ALL) (32 patients, 14%), and chronic lymphocytic leukemia (CLL) (2 patients, 1%). Commercial CAR-T products accounted for 89% of all treatments and were predominantly used for NHL (n = 135) and MM (n = 35). Most deaths were attributed to disease progression or relapse (n = 42), followed by infections (n = 14). After a median follow-up of 365 days, the 1-year OS was 63% (95% CI, 54–73%) among patients with NHL and 73% (95% CI, 57–93%) among patients with ALL. **Conclusion:** This report documents the implementation and rapid expansion of CAR-T cell therapy in Brazil among centers reporting to the SBTMO/CIBMTR network. The continued development of this collaborative infrastructure supports national monitoring of CAR-T activity, facilitates outcome assessment, and contributes to quality assurance, benchmarking initiatives, and compliance with national and international regulatory requirements.

**Keywords:** CAR-T cells; Cancer immunotherapy; Chimeric antigen receptor (CAR); Data management; CIBMTR; SBTMO; Brazilian summary slides.

## INTRODUCTION

Chimeric antigen receptor T cells (CAR-T cells) are genetically modified cellular immunotherapies directed against different antigens expressed in tumor cells. *Agência Nacional de Vigilância Sanitária* (Anvisa), like other national regulatory health authorities, requires recipients of these therapies to be followed for 15 years for assessment of safety, including the development of subsequent neoplasms. On top of possible underlying genetic predisposition and the potential mutagenic effect of prior chemotherapy and irradiation, genetically modified cellular products carry the risk of subsequent malignancies, including insertional mutagenesis or replication of competent retrovirus or lentivirus.[1]

Among the cellular immunotherapy products, the most used and currently approved as standard-of-care treatment are autologous CAR-T cells targeting CD19 for the treatment of non-Hodgkin lymphomas (NHL) and lymphoid leukemia, and BCMA for multiple myeloma (MM). The process involved in CAR-T cell therapies is multi-step, starting with indication, access, washout, leukapheresis, manufacturing, lymphodepleting chemotherapy, infusion, treatment of the specific complications, and long-term follow-up, with special attention to potential neurological late effects and secondary malignancies. In 2019, the Centro de Terapia Celular do Hemocentro de Ribeirão Preto, Universidade de São Paulo, was the first in the country to treat patients under compassionate use of their academic CD19 CAR-T, as the patients with NHL and acute lymphoblastic leukemia (ALL) had exhausted all other treatment options. Many of these patients achieved remission and are still disease-free as of 2026.[2,3]

Since 2020, Anvisa has approved four commercial CAR-T products for leukemia, lymphoma, and myeloma: Kymriah® (anti-CD19 tisagenlecleucel; approval date February 23, 2022), Carvykti® (anti-BCMA ciltacabtagene autoleucel, approval date April 1, 2022), Yescarta® (anti-CD19 axicabtagene ciloleucel, approval date October 26, 2022), and Tecartus® (anti-CD19 brexucabtagene autoleucel, approval date January 30, 2024).

With the publication of the first specific health regulations for advanced therapy products, Brazil has joined the countries with regulatory frameworks for the development and use of these innovative products.[4] There

are nine other Brazilian academic CAR-T cell initiatives discussed elsewhere. According to Anvisa, it is required to conduct a 15-year post-CAR-T cell therapy follow-up. Industries may have different protocols or registries to comply with this unique follow-up requirement.

The Sociedade Brasileira de Terapia Celular e Transplante de Medula Óssea (SBTMO) has a long experience registering hematopoietic cell transplants (HCTs) in partnership with the Center for International Blood and Marrow Transplant Research (CIBMTR), using the North American web-based infrastructure. The first Brazilian CAR-T cell therapy was registered at the CIBMTR in 2020. The CIBMTR includes but does not require research CAR-Ts to be reported. Over the years, the number of Brazilian centers reporting to the CIBMTR has increased, facilitating the establishment of a comprehensive database for evaluating CAR-T cell therapy outcomes in the country. This growth has also contributed to the development of the Registro Brasileiro de Transplante de Células Hematopoéticas e Terapia Celular (RBTCH-TC). Data reported by Brazilian centers to the CIBMTR are aggregated and shared back with the SBTMO. The CAR-T cell therapy activities at Brazilian centers are published annually on the SBTMO website and Journal, providing a valuable resource for the community of advanced cell therapies in Brazil. This initiative enhances collaboration, data sharing, and the progress of cellular therapies in Brazil.

## OBJECTIVE

This study aimed to describe CAR-T cell therapy activity and outcomes reported by Brazilian centers participating in the SBTMO/CIBMTR network from January 2020 to December 2025.

## METHODS

### Data sources

Brazilian advanced cell therapy centers report their data to the CIBMTR, using the electronic FormsNet3 platform. Patients and/or legal guardians provided informed consent. Access is protected by two-factor authentication for all users. The compiled, standardized, and codified data are returned to the SBTMO through the Data Back to Centers (DBtC) tool, enabling the analysis of CAR-T cell outcomes throughout the country.

### Selection

Data from 219 CAR-T cell infusions from January 2020 to December 2025 were extracted from the CIBMTR portal using the DBtC, gathering information from 20 Brazilian centers. There was complete information about the type of CAR-T cell and diagnoses.

Data were imported into Power BI Desktop (Microsoft Corp., Redmond, WA, USA) for data management, descriptive analyses, graphical representation, and variable categorization, including disease classification and the assessment of CAR-T cell activity and participating centers.

### Definitions and outcomes

Age groups were defined as pediatric (0-17 years of age) or adult (≥ 18 years of age).

CAR-T cells were classified as non-commercial and commercial.

Treatment outcomes and causes of death were individually reviewed.

### Statistical analysis

Descriptive statistics were used for categorical data, with the number of cases and percentages. Graphics were generated by PBI. Overall survival (OS) was estimated using the Kaplan–Meier method.

### Ethical considerations

Ethical approval for the utilization of the CIBMTR platform for the annual activity reports using the Brazilian registry was obtained from the national Institutional Review Board (IRB) in 2019 (Comissão Nacional de Ética em Pesquisa CAAE: 65575317.5.1001.0071; principal investigator Nelson Hamerschlak). All patients sign specific consent forms before their personal data are reported to the CIBMTR.

## RESULTS

From January 2020 to December 2025, 219 autologous CAR-T cell infusions were reported from 20 Brazilian centers (Table 1). The median age at infusion was 57 years, ranging from 4 to 83 years. Most patients were adults (n = 199, 91%), while pediatric cases accounted for a smaller proportion (n = 20, 9%). Regarding gender distribution, 131 patients (60%) were male, and 88 (40%) were female (Table 2). A total of 140 patients (64%) had not undergone a previous HCT.

**Table 1.** Reporting CAR-T cell centers.

| Participating centers |
|---|
| A.C. Camargo Cancer Center |
| Complexo Hospitalar de Niterói |
| Fundação Centro Médico de Campinas |
| Hospital 9 de Julho |
| Hospital Brasília |
| Hospital das Clínicas, Faculdade de Medicina, Universidade de São Paulo |
| Hospital de Clínicas, Universidade Estadual de Campinas |
| Hospital DF Star |
| Hospital e Maternidade Brasil |
| Hospital Erasto Gaertner |
| Hospital Israelita Albert Einstein |
| Hospital Nossa Senhora das Graças – Instituto Pasquini |
| Hospital Pequeno Príncipe |
| Hospital Samaritano Higienópolis |
| Hospital São Luiz Itaim |
| Hospital Sírio-Libanês – Brasília |
| Hospital Sírio-Libanês – São Paulo |
| Hospital Vila Nova Star |
| Monte Klinikum Hospital |
| Real e Benemérita Associação Portuguesa de Beneficência |

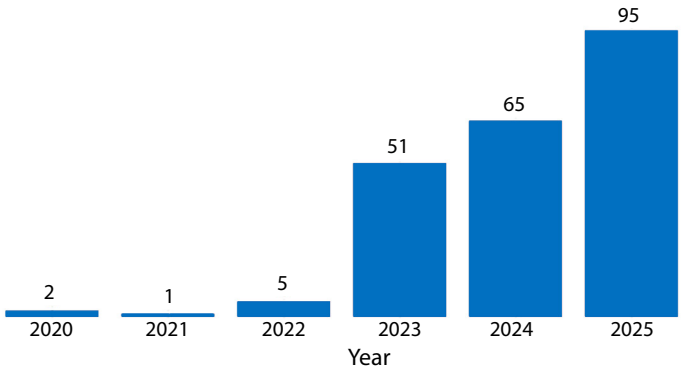
Source: Elaborated by the authors.

There was a notable increase in the number of procedures performed in the country and registered in the CIBMTR: two patients were registered in 2020, one in 2021, five in 2022, 51 in 2023, 65 in 2024, and 95 in 2025 (Fig. 1); 69% (151) were performed in the state of São Paulo, 21% (47) in the state of Paraná, 6% (14) in the state of Rio de Janeiro, 3% (6) in the Distrito Federal, and 1% (1) in the state of Ceará. Adults accounted for 91% (199) of the patients, with a median age at infusion of 60 years (21-83) for NHL, 62 (34-78) for MM, 11 (4-45) for ALL, and 68 (66-69) for CLL. The predominant age group was between 60 and 69 years (Fig. 2). The indications were NHL (146 cases; 67%), MM (39 cases; 18%), ALL (32 cases; 14%), and CLL (2 cases; 1%) (Fig. 3).

**Table 2.** Demographic, disease, and treatment characteristics of CAR-T cell infusions.

| **Characteristic (n = 219)** | | |
|---|---|---|
| Age at infusion, median (range), years | 57 (4-83) | |
| **Adult x pediatric, n (%)** | | |
| Adult | 199 | 91 |
| Pediatric | 20 | 9 |
| **Gender, n (%)** | | |
| Male | 131 | 60 |
| Female | 88 | 40 |
| **Disease, n (%)** | | |
| NHL | 146 | 67 |
| ALL | 32 | 14 |
| Plasma cell disorder (PCD)/MM | 39 | 18 |
| CLL | 2 | 1 |
| **Product name, n (%)** | | |
| Yescarta | 85 | 39 |
| Kymriah | 74 | 34 |
| Carvykti | 35 | 16 |
| No product name | 24 | 11 |
| Tecartus | 1 | < 1 |
| Days from diagnosis to cell therapy infusion, median (range) | 804 (42-8,884) | |
| Days from cell therapy collection and infusion, median (range) | 54 (3-597) | |

Source: Elaborated by the authors.




Source: Elaborated by the authors.

**Figure 1.** Number of CAR-T cell infusions per year.

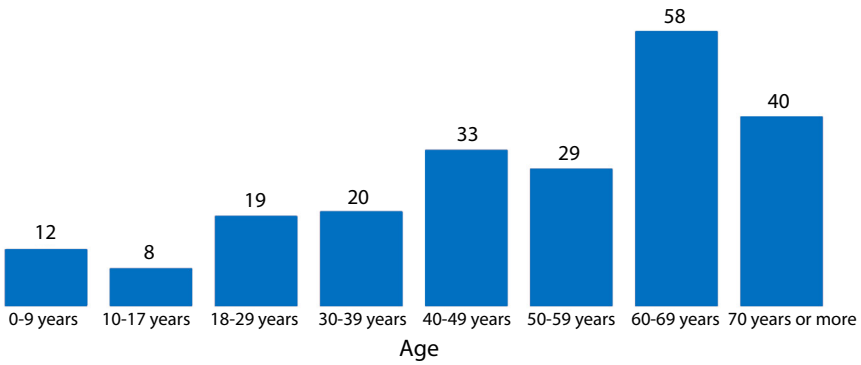



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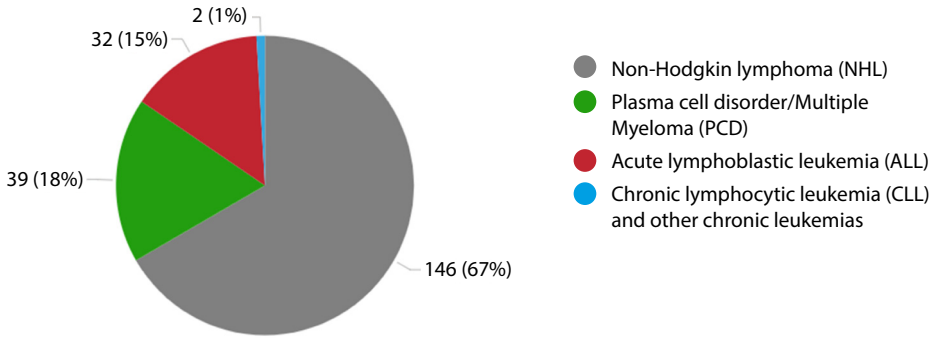
**Figure 2.** Patients' age at CAR-T cell infusion.




Source: Elaborated by the authors.

**Figure 3.** Indications for CAR-T cell therapies.

Among the 219 infusions, 89% were commercial (135 NHL, 35 MM, and 25 ALL) and 11% were academic (11 NHL, 7 ALL, 4 MM, and 2 CLL) (Fig. 4). Previous allogeneic HCT was reported in 75% of patients with ALL and in 50% of patients with CLL. Previous autologous HCT was reported in 64% of patients with MM and in 29% of patients with NHL (Fig. 5). Commercial products (n = 195) were 44% (n = 85) Yescarta® for NHL, 38% (n = 74) Kymriah® (n = 49 for NHL and n = 25 for ALL), 18% (n = 35) Carvykti® for MM, and < 1% (n = 1) Tecartus®. This last patient received Tecartus® in the United States, while their follow-up was conducted in Brazil.

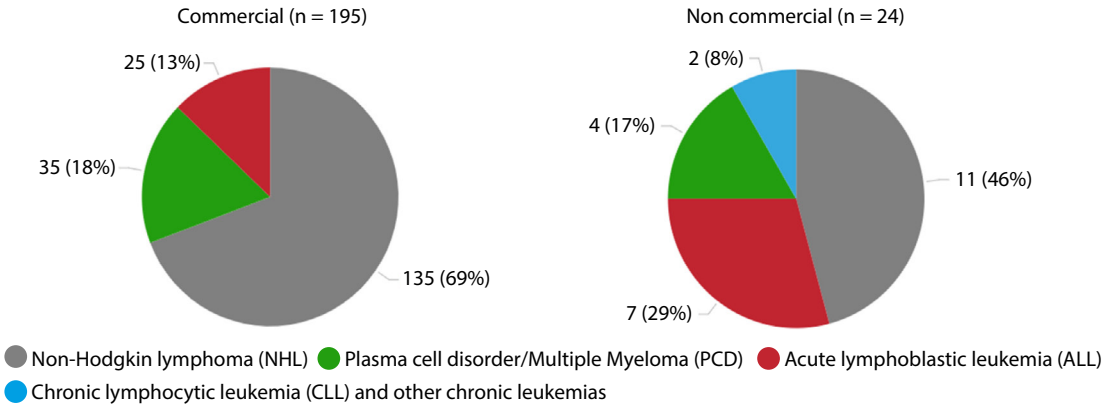



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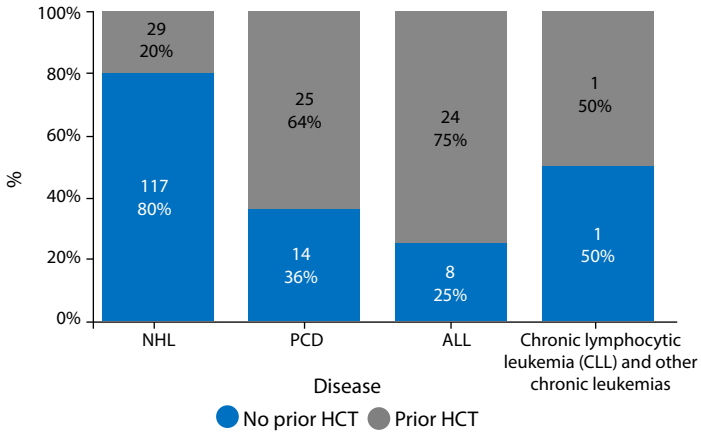
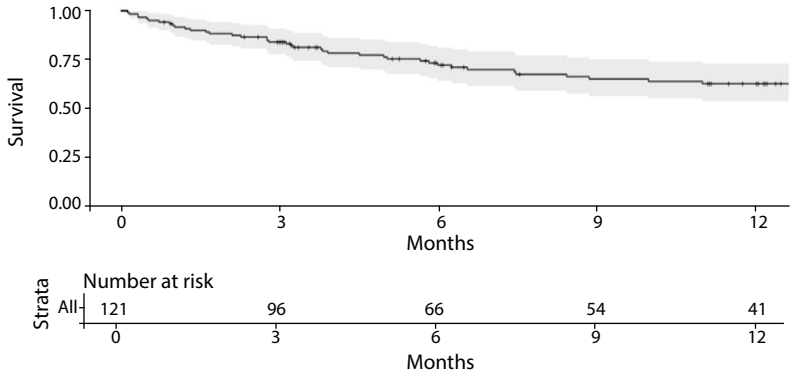
**Figure 4.** CAR-T cell indications by commercial and non-commercial products.




Source: Elaborated by the authors.

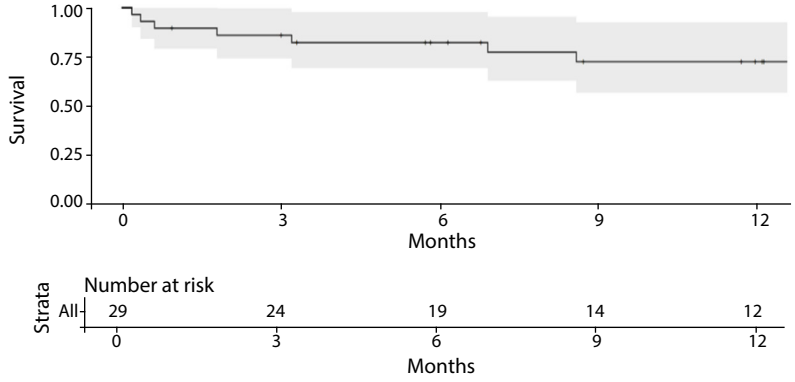
**Figure 5.** Proportion of patients undergoing HCT prior to CAR-T infusion.

The median follow-up for patients who were alive after CAR-T cell therapy was 365 days (range 25-1,100). Of the 121 patients treated for NHL with a reported follow-up, the 1-year OS was 63% (95%CI 54-73) (Fig. 6) and 73% (95%CI 57-93) for ALL (n = 29) (Fig. 7).




Source: Elaborated by the authors.

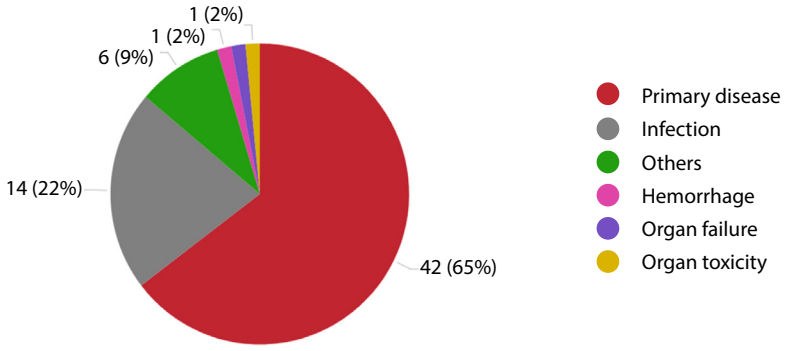
**Figure 6.** OS of patients treated for NHL (at 365 days): 63% (95%CI 54-73).




Source: Elaborated by the authors.

**Figure 7.** OS of patients treated for ALL (at 365 days): 73% (95%CI 57-93).

Disease progression and/or relapse accounted for most deaths (65%, n = 42), followed by infectious complications (22%, n = 14) (Fig. 8).




Source: Elaborated by the authors.

**Figure 8.** Causes of death.

## DISCUSSION

This third annual report of CAR-T cell therapy activity and outcomes in Brazil, based on data from the SBTMO/CIBMTR network, documents 219 infusions performed across 20 Brazilian centers between January 2020 and December 2025. These findings reflect the progressive consolidation of CAR-T cell therapy in the country and provide an important national benchmark for monitoring activity, evaluating clinical outcomes, and assessing access to advanced cellular therapies. From two reported cases in 2020 to 95 reported cases in 2025, and from eight[5] to 20 reporting centers, these findings highlight a clear consolidation of CAR-T therapy infrastructure and growing engagement of Brazilian institutions with international registries such as the CIBMTR. This trend mirrors the early adoption phase described in previous national registry reports, in which initial CAR-T activity was limited but steadily expanding across transplant centers.[5] The comparison with international data (United States, Canada, and Israel) shows a similar distribution of indications, with NHL predominating in adults and ALL in pediatric patients, reinforcing that Brazilian practice is clinically aligned with global patterns.[6]

Despite this growth, the distribution of CAR-T activity in Brazil remains markedly uneven. Similar to what has been observed in HCT, access is predominantly concentrated in the Southeast region, reflecting disparities in infrastructure, accreditation, and specialized workforce availability. National analyses have consistently demonstrated regional inequalities and differences between academic and commercial programs, reinforcing that access to advanced cellular therapies remains highly dependent on geographic and institutional factors.[7]

Another relevant finding is the low proportion of pediatric cases (n = 20), particularly in ALL, which raises concerns beyond expected demographic differences. Although pediatric populations are intrinsically smaller, this number suggests potential structural gaps, including a limited number of accredited pediatric CAR-T centers, challenges in referral pathways, and barriers to integrating pediatric oncology networks into CAR-T programs. These findings warrant further investigation, as timely referral and access are critical determinants of outcomes in relapsed/refractory ALL.

Importantly, when placing these results into a broader epidemiological context, the magnitude of the unmet need becomes evident. According to national cancer estimates, thousands of new cases of NHL are diagnosed annually in Brazil (approximately 6,000–6,500 cases per year for each sex).[8] Even considering that only a fraction of these patients will develop relapsed/refractory disease eligible for CAR-T therapy, the contrast between the expected eligible population and the 219 CAR-T infusions reported between January 2020 and December 2025 in Brazil underscores a major access gap. This discrepancy strongly suggests that CAR-T therapy remains inaccessible to most patients who could benefit from it, representing a substantial barrier.

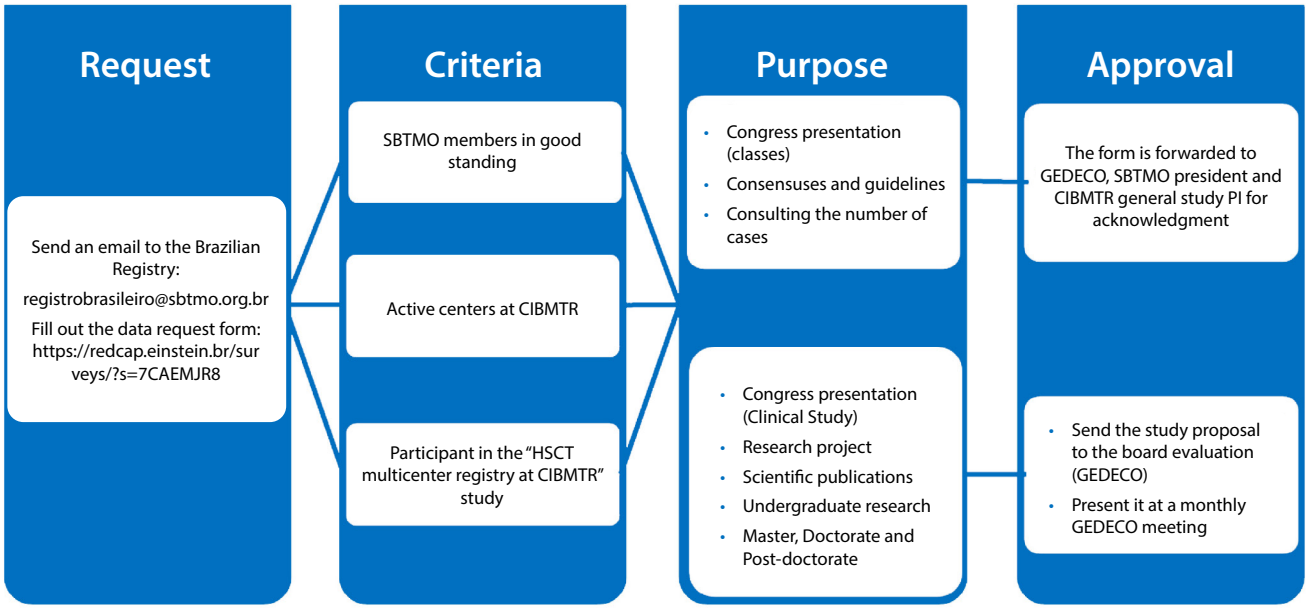
The predominance of commercial CAR-T products (89%) and the limited use of academic platforms (11%) reflect structural and economic constraints, particularly in low- and middle-income settings. High treatment costs, complex logistics, and manufacturing limitations remain key barriers to widespread implementation.[9-11] In Brazil specifically, access to CAR-T therapy is further complicated by systemic factors, including the lack of incorporation into the public health system (Sistema Único de Saúde), limited reimbursement mechanisms, and frequent reliance on judicialization. Legal actions have become a common pathway for patients to access CAR-T therapies, often delaying treatment initiation and creating inequities in access depending on socioeconomic and legal resources.[12] Such delays are critical in rapidly progressive diseases and may directly impact eligibility and outcomes.

Despite access constraints and the relatively short follow-up period, survival outcomes in this cohort were encouraging and consistent with international experience. The 1-year OS of 63% for NHL and 73% for ALL is substantially higher than historical outcomes for relapsed/refractory disease, confirming the transformative potential of CAR-T therapy in real-world practice. Additionally, the leading cause of death was disease progression or relapse (65%), followed by infectious complications (22%), patterns that are comparable to those observed after conventional HCT, reinforcing similarities in post-treatment risk profiles.[6]

This study has limitations that should be considered when interpreting the findings. First, case underreporting may have occurred, as not all centers performing CAR-T cell therapy systematically contribute data to the registry. Second, detailed information regarding treatment-related toxicities and disease-free survival was unavailable, precluding a more comprehensive assessment of the safety and efficacy of CAR-T cell therapy. Third, the relatively short follow-up period limits the evaluation of long-term outcomes. Finally, important metrics related to treatment access could not be assessed, including the interval between treatment indication and CAR-T cell infusion (brain-to-vein time), as well as the number of patients who died while awaiting therapy. These factors may have influenced the observed outcomes and should be considered when interpreting this real-world experience.

These results emphasize the importance of robust data capture and continuous engagement among participating centers. Accurate and comprehensive reporting is essential not only to monitor outcomes but also to support benchmarking, guide healthcare policies, and advocate for expanded access. Strengthening national and international registry collaboration will be critical to better understand real-world effectiveness and to drive improvements in quality of care.

The Brazilian Summary Slides are published yearly and are fully available to active centers in the CIBMTR/RBTCH-TC through the SBTMO data request flow (Fig. 9).




Source: Elaborated by the authors.

**Figure 9.** Data request flow.

## CONCLUSION

The partnership between SBTMO and CIBMTR led to the creation of the RBTCH-TC. Analyses of the Brazilian CAR-T cell data have resulted in the development of these Brazilian Summary Slides, contributing to a deeper understanding of national CAR-T cell outcomes and providing centers with a national reference. These Brazilian Summary Slides are updated annually and published in the open-access online Journal of Bone Marrow Transplantation and Cellular Therapy. Despite differences in the number of reported cases, the distribution of indications, causes of death, and survival outcomes were broadly consistent with those reported in the U.S. Summary Slides. Consolidation of the registry is promising, as evidenced by the growing number of Brazilian centers affiliated with the CIBMTR and the enhanced qualifications of the data

managers (DMs) nationwide. Nevertheless, significant work remains ahead. Enhancing the commitment of CAR-T cell centers to report data is paramount to optimizing the transplant registry, as well as ensuring long-term follow-up and providing continuous education to DMs, thus fostering the retrieval of high-quality data within the national registry. Governmental support, including resources, infrastructure, and training, is indispensable to attain these objectives. Sustained and unwavering dedication to this endeavor holds the potential for ongoing improvements within the SBTMO data registry, ultimately resulting in better care for our patients. Our current challenge is to help all Brazilian centers involved in CAR-T cell therapies register data with the CIBMTR-SBTMO, so that this national initiative can be strengthened, as has already been done with HCT data.

## CONFLICTS OF INTEREST

Nothing to declare.

## AUTHOR CONTRIBUTIONS

**Conceptualization:** Silva CC, Simione AJ, Fatobene G, Schmidt Filho J, Seber A, Hamerschlak N, Duarte FB. **Investigation:** Silva CC, Simione AJ, Fatobene G, Schmidt Filho J, Seber A, Hamerschlak N, Farias JSH, Funke VAM, Scheinberg P, Moreira MCR, Costa Neto A, Molla VC, Dumke CCK, Novis YAS, Rocha V, Ferreira FB, Vilela VAL, Grilo GV, Melo AL, Ribeiro AAF, Colella MP, Vigorito AC, Pasquini MC, Duarte FB. **Methodology:** Silva CC, Simione AJ, Fatobene G, Schmidt Filho J, Seber A, Hamerschlak N, Duarte FB. **Formal Analysis:** Simione AJ. Data Curation: Simione AJ. **Project Administration:** Silva CC, Simione AJ, Seber A, Hamerschlak N, Pasquini MC, Duarte FB. **Funding Acquisition:** Not applicable. **Writing:** Silva CC, Simione AJ, Fatobene G, Schmidt Filho J, Seber A, Hamerschlak N, Duarte FB. **Supervision:** Hamerschlak N, Duarte FB. **Final Approval:** Silva CC, Simione AJ, Fatobene G, Schmidt-Filho J, Seber A, Hamerschlak N, Farias JSH, Funke VAM, Scheinberg P, Moreira MCR, Neto AC, Molla VC, Dumke CCK, Novis YAS, Rocha V, Ferreira FB, Vilela VAL, Grilo GV, Melo AL, Ribeiro AAF, Colella MP, Vigorito AC, Pasquini MC, Duarte FB.

## DATA AVAILABILITY STATEMENT

Nothing to declare.

## FUNDING

This research did not receive any specific funding from public, commercial, or not-for-profit funding agencies.

## DECLARATION OF USE OF ARTIFICIAL INTELLIGENCE TOOLS

The authors declare that artificial intelligence (AI) tools were used solely to assist with language editing, grammar refinement, and clarity of expression during manuscript preparation. No AI tools were used for data analysis, interpretation of results, or generation of scientific content. The authors retain full responsibility for the content of this manuscript.

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## FINANCIAL DISCLOSURE

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