BRIEF REPORT

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National Perspectives on Academic CAR-T Cell Therapy in Türkiye: A Report from the Turkish Society of Hematology's Scientific Subcommittee on Cell and Gene Therapies (TSH-CGT SSC)

Türkiye'de Akademik CAR-T Hücre Tedavisine İlişkin Ulusal Perspektifler: Türk Hematoloji Derneği, Hücre ve Gen Tedavileri Bilimsel Alt Komitesi (TSH-CGT SSC) Raporu

Meltem Kurt Yüksel[1], Koray Yalçın[2], Tuğrul Elverdi[3], Mahmut Yeral[4], Nur Akad Soyer[5], Şahika Zeynep Aki[6], Fatma Visal Okur[7], Muhlis Cem Ar[3]

[1]*Ankara University Faculty of Medicine, Department of Hematology and Stem Cell Transplantation Unit, Ankara, Türkiye*
[2]*Medical Park Hospitals, Clinic of Pediatric Hematology and Oncology, İstanbul, Türkiye*
[3]*İstanbul University-Cerrahpaşa, Cerrahpaşa Faculty of Medicine, Department of Hematology and Stem Cell Transplantation Unit, İstanbul, Türkiye*
[4]*Başkent University Faculty of Medicine, Department of Hematology and Stem Cell Transplantation Unit, Adana, Türkiye*
[5]*Ege University Faculty of Medicine, Department of Hematology and Stem Cell Transplantation Unit, İzmir, Türkiye*
[6]*University of Health Sciences Türkiye, Ankara Etlik City Hospital, Clinic of Hematology and Stem Cell Transplantation Unit, Ankara, Türkiye*
[7]*Hacettepe University Faculty of Medicine, Department of Pediatric Hematology and Oncology, Ankara, Türkiye*

Abstract

This study evaluated the current status, clinical capacity, and key barriers related to chimeric antigen receptor T-cell (CAR-T) therapy in Türkiye with the aim of guiding national policy development. From June 2023 to March 2024, the Scientific Subcommittee on Cell and Gene Therapies of the Turkish Society of Hematology conducted two nationwide online surveys and held three multidisciplinary meetings with contributions from hematologists, basic scientists, and key stakeholders. Survey findings were integrated with the meeting outputs and recent regulatory developments. Surveys indicated a marked gap between the estimated annual need (about 507 patients) and actual access to CAR-T therapy. Between 2019 and March 2024, only 23 patients in Türkiye received CAR-T therapy. Major barriers included high treatment costs, insufficient infrastructure, and a limited number of trained personnel. Expert meetings further highlighted challenges with regulatory pathways, reimbursement, and the need for standardized production and clinical protocols. Despite these limitations, participants demonstrated strong clinical readiness and consensus on the need to improve access. The implementation of CAR-T therapy in Türkiye continues to be impeded by structural and economic limitations. It is imperative to develop a strategic national roadmap that encompasses: 1) the establishment of a national academic CAR-T network, 2) the securing of sustainable funding and legal frameworks, 3) the implementation of hospital-exemption pathways, 4) the development of a centralized registry, 5) the expansion of structured training programs, and 6) the enhancement of

Öz

Bu çalışmanın amacı, Türkiye'de kimerik antijen reseptörlü T-hücre (CAR-T) tedavisinin mevcut durumunu, klinik kapasitesini ve başlıca kısıtlayıcı faktörleri değerlendirmek ve ulusal politika geliştirme süreçlerine bilimsel veri sağlamaktır. Haziran 2023-Mart 2024 döneminde, Türk Hematoloji Derneği Hücre ve Gen Tedavileri Bilimsel Alt Komitesi tarafından ülke çapında iki çevrimiçi anket uygulanmış ve hematologlar, temel bilimciler ile ilgili paydaşların katılımıyla üç multidisipliner toplantı gerçekleştirilmiştir. Elde edilen anket verileri, toplantı çıktıları ve güncel düzenleyici gelişmelerle bütüncül olarak analiz edilmiştir. Anket bulguları, yıllık tahmini ihtiyaç (yaklaşık 507 hasta) ile CAR-T tedavisine erişim arasında belirgin bir uyumsuzluk olduğunu ortaya koymaktadır. 2019 ile Mart 2024 tarihleri arasında Türkiye'de yalnızca 23 hastaya CAR-T tedavisi uygulanmıştır. Başlıca kısıtlayıcı faktörler; yüksek tedavi maliyetleri, yetersiz kurumsal altyapı ve sınırlı sayıda eğitimli insan kaynağı olarak belirlenmiştir. Uzman toplantılarında ayrıca düzenleyici süreçlerdeki belirsizlikler, geri ödeme mekanizmalarındaki yetersizlikler ve standartlaştırılmış üretim ile klinik uygulama protokollerine duyulan gereksinim vurgulanmıştır. Tüm bu sınırlılıklara karşın, katılımcılar güçlü bir klinik hazırlık düzeyine sahip olduklarını ve erişimin artırılması gerekliliği konusunda yüksek düzeyde görüş birliği bulunduğunu ifade etmiştir. Türkiye'de CAR-T tedavisinin klinik uygulamaya entegrasyonu, yapısal ve ekonomik sınırlılıklar nedeniyle halen kısıtlıdır. Bu bağlamda, sürdürülebilir bir ulusal stratejik yol haritasının geliştirilmesi kritik önem taşımaktadır. Bu yol haritası kapsamında; 1) ulusal akademik CAR-T ağının oluşturulması, 2) sürdürülebilir finansman modelleri

Address for Correspondence/Yazışma Adresi: Meltem Kurt Yüksel, M.D., Ankara University Faculty of Medicine, Department of Hematology and Stem Cell Transplantation Unit, Ankara, Türkiye
E-mail: meltemkurt@hotmail.com **ORCID:** orcid.org/0000-0003-0369-299X

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Abstract

international collaborations. These measures are fundamental for the sustainable integration of this therapy into clinical practice.

Keywords: CAR-T cell therapy, Advanced therapy medicinal products, Academic production, Hospital exemption, Türkiye, Strategy, Survey, Meeting

Öz

ve destekleyici yasal düzenlemelerin hayata geçirilmesi, 3) hastane muafiyeti (hospital exemption) mekanizmalarının uygulanması, 4) merkezi bir ulusal kayıt sisteminin kurulması, 5) yapılandırılmış eğitim programlarının yaygınlaştırılması ve 6) uluslararası iş birliklerinin güçlendirilmesi temel öncelikler olarak öne çıkmaktadır.

Anahtar Sözcükler: CAR-T hücre tedavisi, ATMP, akademik üretim, hastane muafiyeti, Türkiye, strateji, anket, toplantı

Introduction

Advanced therapy medicinal products (ATMPs) constitute a transformative class of biological therapies, with chimeric antigen receptor (CAR)-T cell therapy marking a major milestone in hematological oncology [1,2]. The first CAR-T protocol for chronic lymphocytic leukemia was developed in 2008, with the initial treated patient surviving 11 years before dying from coronavirus disease 2019 at age 75 [3,4]. Currently, more than 1500 CAR-T clinical trials are registered worldwide, with expanding applications in solid tumors and autoimmune diseases [5]. By 2023, approximately 13,000 patients in Europe with B-cell lymphoma (BCL), multiple myeloma (MM), and acute lymphoblastic leukemia (ALL) had received CAR-T therapy [6,7]. Despite substantial progress, however, access to CAR-T cell therapies remains constrained by patient-specific manufacturing, high costs, and technological complexity. This report evaluates the CAR-T manufacturing landscape and regulatory environment in Türkiye, where only two academic CAR-T centers currently serve a population of approximately 85 million [8]. In contrast, Spain's ARI-0001 academic CAR-T program has shown that national coordination, regulatory flexibility, and governmental support can enable safe, effective, and cost-efficient domestic production [9]. To address the existing gaps, the Turkish Society of Hematology's Scientific Subcommittee on Cell and Gene Therapies conducted nationwide surveys and stakeholder meetings to assess awareness, readiness, and barriers, providing a policy-oriented snapshot of CAR-T therapy in Türkiye.

Materials and Methods

Between June 2023 and March 2024, three meetings were organized: an Ankara workshop on CAR-T therapy, an İstanbul meeting focusing on production models with international experts, and a CAR-T training session in Antalya during the National Bone Marrow Transplantation and Cellular Therapies Congress [5,9].

Two anonymous nationwide surveys were conducted via SurveyMonkey to assess clinician awareness, demand, and referral practices. Survey details are provided in Supplements 1 and 2. Although the survey results are not the primary focus of this study, they support needs assessment and policy discussions.

The estimated annual need for CAR-T therapy was calculated based on responses to the following question: "Based on current guidelines, how many patients would you have needed to treat with CAR-T over the past year?" (Supplement 3, question S7).

Ethics Committee Approval

The study was approved by the Ege University Medical Research Ethics Committee (decision no: 26-1T/15, 8 January 2026).

Statistical Analysis

Participation was voluntary and anonymous. Descriptive statistical methods were used.

Results

Surveys

A total of 172 healthcare professionals participated in this study (100 in Survey 1, 72 in Survey 2), including adult hematologists (82%), pediatric hematologists (16%), and basic scientists (2%) from 16 provinces, primarily İstanbul (35%) and Ankara (21%). While 60% had more than 10 years of experience, 69% reported no structured training in cellular therapies.

The estimated national annual need for CAR-T therapy was approximately 507 patients. However, only 23 patients received CAR-T therapy in Türkiye between 2019 and March 2024. Of these, 9 patients (2 with ALL, 7 with lymphoma) were treated within an academic clinical trial, while 14 patients (7 with ALL, 7 with lymphoma) were referred abroad, primarily to Germany.

The main barriers identified were high treatment costs (65%), inadequate institutional infrastructure (21%), and insufficient trained personnel (7%). Despite these limitations, 98% of respondents indicated willingness to refer eligible patients if domestic access were available, and 97% reported that access barriers significantly limit routine use.

Meetings

The first meeting provided an overview of advanced therapies and CAR-T clinical outcomes, followed by discussions on research, manufacturing, quality control, and good manufacturing practice (GMP) challenges. Legal frameworks, ethical considerations,

and training needs were also addressed. Key issues identified included limited national experience, funding constraints, and regulatory gaps. The workshop details and final report are provided in Supplements 4 and 5.

The second meeting, titled "Current Status of Cell and Gene Therapy Products in Hematological Malignancies," included national stakeholders and international experts, as well as representatives from the Türkiye Health Institutes (TÜSEB), the Scientific and Technological Research Council of Türkiye, the Turkish Medicines and Medical Devices Agency, the Ministry of Health, and industry organizations (Association of Research-Based Pharmaceutical Companies). Topics included European phase I/II trial outcomes, real-world challenges, and production models (centralized vs. decentralized). European Union-funded projects such as T2Evolve, autologous versus allogeneic CAR-T approaches, and Spain's experience were discussed. Emphasis was placed on automation technologies, leukapheresis, quality control, and regulatory updates. The symposium details and final report are included in Supplements 6 and 7.

The third meeting in Antalya, sponsored by Türkiye's first academic CAR-T center, focused on practical manufacturing processes and real-world challenges, supported by structured video-based procedural demonstrations illustrating critical CAR-T manufacturing steps, process controls, and operational quality requirements (Supplement 8). The activities are briefly outlined in Figure 1 for a quick overview.

Discussion

This study reveals a gap between the need for CAR-T therapy and its availability in Türkiye. Despite high clinician awareness and willingness to refer, access is limited by the infrastructure, workforce, and economic barriers.

Türkiye's recent ATMP regulations [10,11] establish a solid legal foundation for the development of CAR-T therapies. Two main production pathways are available: industrial clinical trials and hospital-exemption models, the latter facilitating rapid academic use [7]. Türkiye's first academic CAR-T trial (ISIKOK-19) was approved through a case-based trial, similar to the hospital-exemption approach, allowing individual access to CAR-T treatments [12,13]. Recent initiatives by TÜSEB, public hospitals, and private centers demonstrate increasing engagement with advanced cellular therapies [14,15]. Since 2017, CAR-T therapy has been approved for BCL, MM, and ALL [16], and it is recommended in current guidelines [17,18,19].

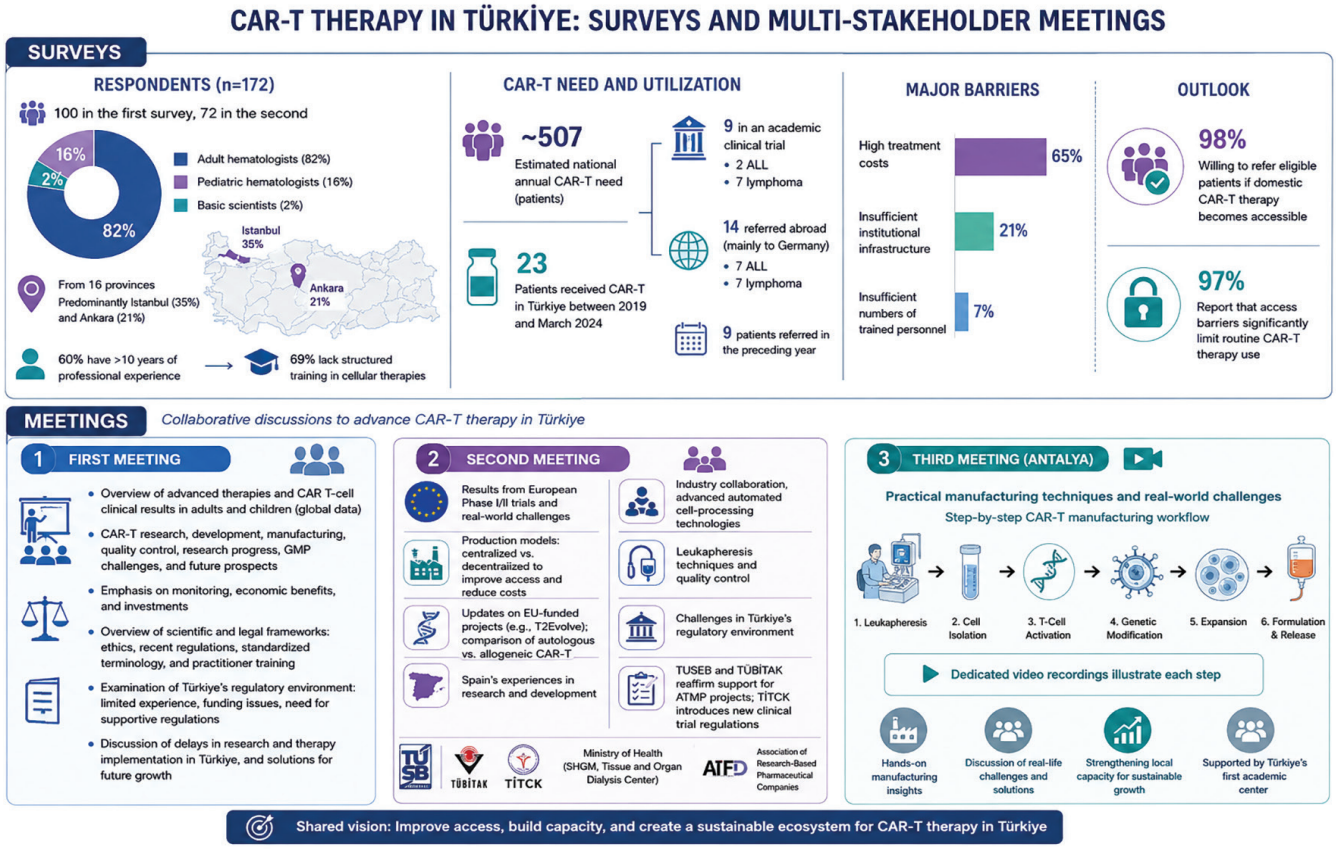


Figure 1. Multidisciplinary evaluation of chimeric antigen receptor T-cell (CAR-T) and advanced therapy ecosystems in Türkiye: structure of meetings, stakeholder participation, and survey findings.

ALL: acute lymphoblastic leukemia; GMP: good manufacturing practice; TÜSEB: Türkiye Health Institutes; TÜBİTAK: Scientific and Technological Research Council of Türkiye; TİTCK: Turkish Medicines and Medical Devices Agency; AIFD: Association of Research-Based Pharmaceutical Companies.

However, high costs continue to be a significant limitation [20]. Globally, the United States reports the highest costs, followed by Europe and China, while India has developed some of the most cost-effective models [21,22]. The United Kingdom's recent legislation supporting domestic production of low-cost CAR-T therapies presents a relevant model [23]. Although economic factors are primary barriers in Türkiye, financing was beyond the scope of this study. Sustainable implementation will require cost-effectiveness analyses and reimbursement strategies through health insurance systems, particularly the Turkish Social Security Institution.

A hybrid model that combines Spain's hospital-exemption approach, China's state-supported production, and India's cost-efficient collaborations may be applicable to Türkiye. The recent removal of Risk Evaluation and Mitigation Strategy requirements for autologous CAR-T therapies by the U.S. Food and Drug Administration reflects growing clinical maturity [24]. Integration with international platforms such as the GoCART Coalition [25] could further enhance collaboration, standardization, and training.

A strategic national plan should be established to create a CAR-T registry to track outcomes, guide policy, and support expansion. Scaling requires sustainable funding, legal and regulatory frameworks, GMP standards, and a centralized data registry. The building of a trained workforce and international collaboration are essential for safe, effective, global CAR-T programs. Figure 2 illustrates an evidence-informed strategic framework for national CAR-T program implementation.

Study Limitations

This study is based on voluntary, self-reported survey data from only 16 provinces, which may not fully represent all hematology centers in Türkiye and is subject to selection and reporting bias. The estimated annual need reflects clinician perception rather than epidemiological data. Only descriptive statistics were used. Cost-effectiveness and health technology assessments were not included and require further study.



Figure 2. Evidence-informed strategic framework for national CAR-T program implementation: registry-based outcome surveillance, regulatory harmonization, good manufacturing practice (GMP)-compliant manufacturing, workforce development, sustainable financing, and international integration.

Conclusion

Türkiye shows strong clinical awareness and growing expertise in CAR-T therapy, but access is limited by economic, infrastructural, and workforce constraints. Updated regulations and national strategies are vital for sustainable growth. This study offers a key foundation for policy development in cellular therapies.

Ethics

Ethics Committee Approval: The study was approved by the Ege University Medical Research Ethics Committee (decision no: 26-1T/15, 8 January 2026).

Informed Consent: All participants and survey respondents participated voluntarily by responding to the announcements.

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Footnotes

Authorship Contributions

Surgical and Medical Practices: M.K., K.Y., T.E., M.Y., N.A.S., Ş.Z.A., F.V.O., M.C.A.; Concept: M.K., M.C.A.; Design: M.K., K.Y.; Data Collection or Processing: M.K., K.Y., T.E., M.Y., N.A.S., Ş.Z.A., F.V.O.; Analysis or Interpretation: M.K., K.Y., T.E., M.Y., N.A.S., Ş.Z.A., F.V.O.; Literature Search: M.K., K.Y.; Writing: M.K., K.Y., M.C.A.

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Supplement 1: https://d2v96fxpocvxx.cloudfront.net/d363ec1e-9e5e-4591-a00a-d656bfcabb80/content-images/41a74a83-3ee7-4c3a-aa96-e8fbebcdcd5f.pdf

Supplement 2: https://d2v96fxpocvxx.cloudfront.net/880a6a1d-b717-4aa8-9d4a-4dfca73fb9c8/content-images/641031a8-fc8b-4cc5-b679-4421d85ec104.pdf

Supplement 3: https://d2v96fxpocvxx.cloudfront.net/d363ec1e-9e5e-4591-a00a-d656bfcabb80/content-images/f7947b51-6fbc-4c8f-a092-d5b92ca8dc2e.pdf

Supplement 4: https://d2v96fxpocvxx.cloudfront.net/880a6a1d-b717-4aa8-9d4a-4dfca73fb9c8/content-images/ef8340e8-bcc6-4ce6-8283-a828e7bfd430.pdf

Supplement 5: https://d2v96fxpocvxx.cloudfront.net/880a6a1d-b717-4aa8-9d4a-4dfca73fb9c8/content-images/8ef98456-ed08-42f7-8b0e-5b1d57ce3850.pdf

Supplement 6: https://d2v96fxpocvxx.cloudfront.net/d363ec1e-9e5e-4591-a00a-d656bfcabb80/content-images/2037246d-cd31-41d8-9642-7d6133adc979.pdf

Supplement 7: https://d2v96fxpocvxx.cloudfront.net/d363ec1e-9e5e-4591-a00a-d656bfcabb80/content-images/42ad30f0-78e7-47dd-ac8c-125069dddc51.pdf

Supplement 8: https://d2v96fxpocvxx.cloudfront.net/d363ec1e-9e5e-4591-a00a-d656bfcabb80/content-images/ec25668e-0b02-4356-8bf5-62b3018fa590.pdf

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