

# Optimizing post-treatment monitoring following CAR T-cell therapy: Policy changes and adverse event data








Due to the risk of CRS and neurological toxicities, approved CAR T-cell therapies were previously only available under the REMS safety program.<sup>1,2</sup>



On June 27, 2025, the FDA removed the REMS requirements for all approved BCMA- and CD19-directed autologous CAR T-cell therapies, based on consistent safety data from clinical trials and real-world studies.<sup>1,2</sup>

## Key requirements for autologous CAR T-cell therapies before and after the FDA removal of REMS<sup>3</sup>

	Before	After
 Institutional certification	Required at REMS-approved sites	Not required
 Tocilizumab availability	On-site and immediately accessible	Not required
 Prescriber / staff training	REMS-specific certification	Integrated into product labelling
 Patient proximity to a healthcare facility after infusion	4 weeks within a 2-hour radius (often stricter in practice)	2 weeks within reasonable proximity
 Driving restriction	8 weeks	2 weeks

## Optimizing post-CAR T-cell monitoring<sup>4</sup>

An analysis by Kamdar *et al.* assessed the timing of CRS and ICANS in patients treated with liso-cel in clinical trials or real-world SoC settings using the CIBMTR registry.

Population:  
N = 1,579

### Clinical trial data (n = 702)

### CIBMTR registry data\* (n = 877)

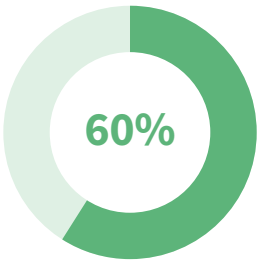
Pooled data from 5 trials of liso-cel in patients with R/R LBCL, CLL/SLL, FL, and MCL (TRANSCEND NHL-001, TRANSCEND CLL-004, TRANSFORM, PILOT, TRANSCEND FL)

Patients with R/R LBCL who received liso-cel and had ≥1 reported assessment after infusion

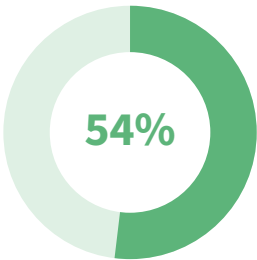
\*Data were collected between February 2021 and May 2024.

## CRS and ICANS

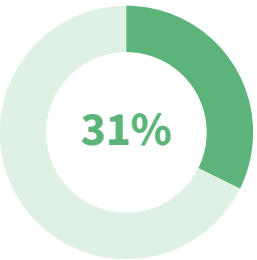
### CRS and NEs



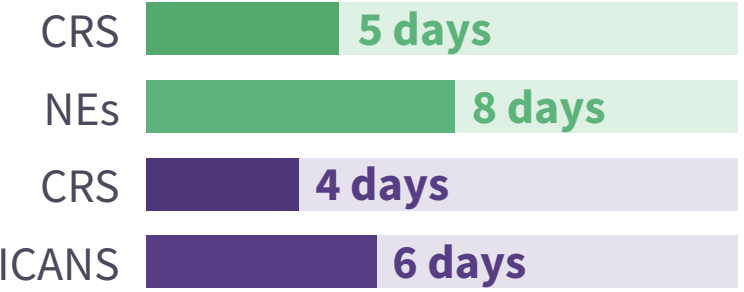
### CRS



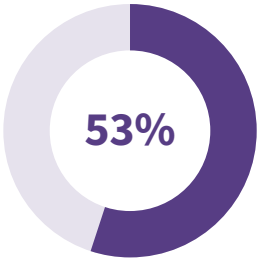
### NEs



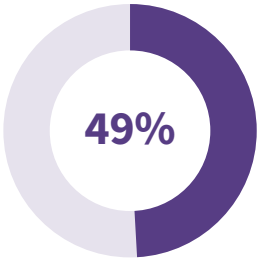
### Median time to onset



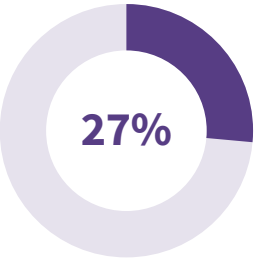
### CRS and ICANS



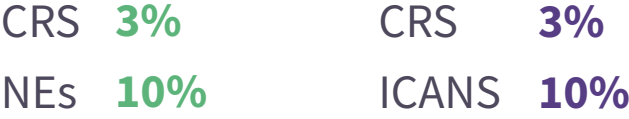
### CRS



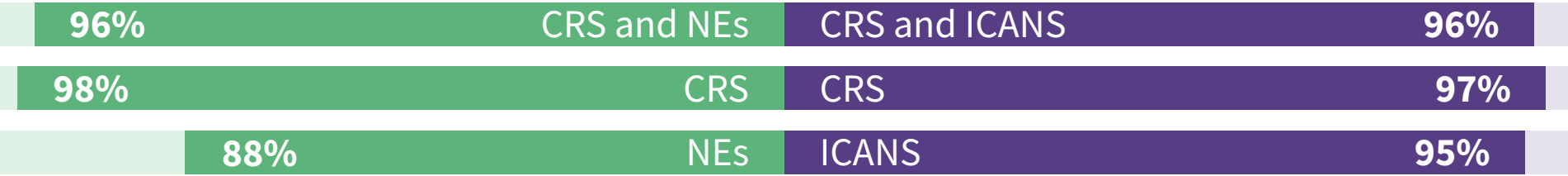
### ICANS



### Maximum Grade ≥3



## Onset within 15 days of infusion



The analysis demonstrates that most CRS/NEs/ICANS events occurred within 15 days of liso-cel infusion and most were not severe. These data support new policy requirements introduced following the FDA removal of REMS (patients to remain within a reasonable proximity to a healthcare facility and not drive for 2 weeks).<sup>3,4</sup> The removal of the REMS requirement for approved autologous CAR T-cell therapies, and data to inform optimal monitoring requirements, may help expand access to these therapies while maintaining patient safety.<sup>3</sup>

**Abbreviations:** BCMA, B-cell maturation antigen; CAR, chimeric antigen receptor; CIBMTR, Center for International Blood and Marrow Transplant Research; CLL, chronic lymphocytic leukemia; CRS, cytokine release syndrome; FDA, U.S. Food and Drug Administration; FL, follicular lymphoma; ICANS, immune effector cell-associated neurotoxicity syndrome; LBCL, large B-cell lymphoma; liso-cel, lisocabtagene maraleucel; MCL, mantle cell lymphoma; NE, neurological event; REMS, Risk Evaluation and Mitigation Strategies; R/R, relapsed/refractory; SLL, small lymphocytic lymphoma; SoC, standard of care.

**References:** **1.** FDA. <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor>. Published Jun 26, 2025. Accessed Dec 1, 2025; **2.** FDA. <https://www.fda.gov/news-events/press-announcements/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor>. Published Jun 27, 2025. Accessed Dec 1, 2025; **3.** Orosco-Ttamina AL, *et al.* *Cancers (Basel)*. 2025;17(19):3216; **4.** Kamdar M. Poster Abstract #7026. 2025 ASCO Annual Meeting; May 30 – Jun 3, 2025; Chicago, US.