# Characterizing the Latency Period of Secondary Primary Malignancy and Lymphoma Onset Following Tisagenlecleucel (CAR-T Cell Therapy): A Real-World Data Analysis

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**Objective**: To characterize the latency period of diagnosis of second primary malignancy and lymphoma following Tisagenlecleucel administration, using the WHO's Vigibase database, and to identify its association factor of Information Component (IC).

**Methods:** A retrospective analysis was conducted on all reported cases of Tisagenlecleucel and second primary malignancy and lymphoma retrieved from the World Health Organization (WHO) database via signal detection tool "Vigibase" and the National Pharmacovigilance Center (NPC) database from the first reported case on 2018 up to 6th of April, 2025.

**Results:** Local cases**:** No local cases were identified in the National Pharmacovigilance Center (NPC) database. Global Cases: the search in the World Health Organization (WHO) database "Vigibase" resulted in 98 Individualized Case Safety Reports (ICSRs). The mean age was 50 years (range 7– 78 years). Among cases, 79 patients (79.6%) developed a second primary malignancy and 19 patients (19.4%) developed Lymphoma. Disproportionality analysis of Information Component (IC) resulted in a value of 5.5 with all ICSRs classified as serious, and 43.88% were classified as fatal (n = 43). The mean time-to-onset between the administration of Tisagenlecleucel and the diagnosis was 7.3 months (range 1 –24 months).

**Conclusion:** The distinct result with the IC value of 5.5 suggests a potential Tisagenlecleucel-related risk of second primary malignancy and lymphoma, demanding close post-marketing surveillance starting as early as one month post-infusion. Further studies utilizing real-world data are crucial to identify predictive factors for secondary primary malignancy and lymphoma in survivors treated with Tisagenlecleucel.