

Leveraging DATAcc by DiME's ontology for data transfer specifications development for early detection of CRS in CAR-T and BiTE therapy patients



About Organization

[Takeda](#) is a patient-focused, values-based, R&D-driven global biopharmaceutical company committed to bringing people better health and a brighter future worldwide.



The opportunity

Patients with hematologic malignancies receiving CAR-T or BiTE products are at risk for developing Cytokine Release Syndrome (CRS), a potentially life-threatening condition. Continuous vital sign monitoring can lead to earlier detection of adverse events, such as fever, hypotension, and tachycardia, enabling timely intervention to prevent CRS progression.

Our observational study aims to illustrate the feasibility of using the TempTraq and VitalTraq devices to provide continuous, real-time data on vital signs in our target patient population. Remote monitoring devices can enhance patient experience, expand clinical trial inclusivity, and allow treatments to reach diverse populations, potentially shifting care to outpatient settings.



The challenge

The complexity and diversity of data types needed for collection to detect CRS, along with the variety of collection methods posed a significant challenge.

Each CRS measurement variable involves careful collection and interpretation. For example, blood pressure is a well-known vital sign; however, additional factors must be considered and collected at the same time, such as measurement interval, time of baseline collection, and other metadata such as the device placement.

The need for a standardized approach to data collection and interpretation was paramount to ensure the reliability and validity of the study outcomes.





The success

- ✓ The ontology for early warning signs of CRS was invaluable in filling the gaps in our data collection process and enhancing the comprehensiveness of our data transfer specifications. We developed a more detailed and structured approach to collecting data from digital wearable measurements and clinical sources.
- ✓ The ontology's structured approach helped us ensure that all relevant data fields, such as vital sign measurements, collection frequency, methods of collection, and relevant clinical data points, were included in the DTS. This comprehensive data collection and transfer process enabled us to see the whole picture of the patient's condition and the factors influencing CRS risk.
- ✓ The DiMe ontology can be a foundational baseline for future studies and reduce the burden of identifying which data fields to collect. By providing a standardized framework, the ontology ensures consistency and comprehensiveness in data collection and facilitates data comparability across studies. This will enhance the robustness of study outcomes and accelerate the development of reliable early warning and risk prediction tools for CRS.

“ Leveraging DiMe's ontology for data transfer specifications and standardizing data collection ensures uniform collection of all variables and enhances the reliability and comprehensiveness of our study observations.

This advancement paves the way for future research, ensuring Takeda remains at the forefront of innovative healthcare solutions.”

— **Erik Koenig**

*Head, PTM Strategic Innovation,
Takeda*

— **Melinda Chen**

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