

Standards needed for clinical data specific to cell therapy

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Abstract

Since the 1st CAR-T cell therapy was approved in 2017 for acute lymphocytic leukemia, there have been hundreds of cell therapy clinical trials every year for different diseases. However, up to now, there are no CDISC standards for the data specific to cell therapy. In this poster, some examples of cell therapy data collection (CRFs) and SDTM mappings will be presented. We recommend that a CDISC and PHUSE joint working group be initiated to develop standards for cell therapy-specific data. It would improve data quality, , reduce costs, and facilitate data sharing and regulatory review.

CAR-T Study Design as example



Examples: Collecting data specific to CAR-T, SDTM mapping, and ADaM

- Leukapheresis data: collected in PR module, but blood volume variables and Donation ID are **not** CDASH. Add PRADDON module.
- CRS/ICANS:
 - Besides AE, **Signs/Symptoms** and **ASTCT CRITERIA** modules are added and mapped to FA/CE SDTM domains, while custom domains are used by Kite.
 - ADCRSNT for analysis of CRS & ICANS, as recommended by FDA ?
(<https://www.fda.gov/media/133252/download>)

Recommendations

Creating standards for cell therapy clinical data is essential to ensure consistency, interoperability, and comparability of data across different cell therapy programs and research studies.

A working group consisting of PHUSE, CDISC, FDA, and pharmaceuticals will be needed to work on CDISC compliant standards from raw data collection to analysis datasets. This collaboration can help ensure that the standards are comprehensive, practical, and widely accepted within the industry, as well as regulatory authorities.