SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

Temperature Excursion Management

The ability to track the temperature excursions of each unit of investigational product is important to ensure that patients are only exposed to medications that are within known stability conditions. While temperature monitoring during transit and at each storage point is performed routinely, it is more difficult to combine these data to allow for the full temperature exposure data for each mediation unit to be reviewed.

Our Temperature Excursion Management (TEM) enables end-to-end excursion tracking for clinical trial medications throughout a study's entire supply chain cycle.

End-to-end tracking
Provide cumulative excursion monitoring and tracking record throughout the entire clinical supply chain cycle

Custom excursion thresholds
Implement drug-specific excursion thresholds based on individual stability profiles

Seamless integration into workflow
Incorporate temperature monitors during the pick-and-pack and logistics processes

Why utilize Signant's Temperature Excursion Management?

The current methods for monitoring and managing IP temperature excursions in clinical trials are fragmented and limit consideration only to excursions within a single location or shipment, use basic rules to flag excursions, and require manual consolidation of different data sources to obtain the full temperature excursion profile.

Signant's TEM solves these challenges by providing a full longitudinal record and audit trail, as well as tracking and consolidated temperature information from transit, warehouse, or site.

Our TEM also supports using generic and medication-specific excursion profiles, which enables sophisticated monitoring within mixed shipments along with comprehensive quarantine management and adjudication when excursions are identified.

Temperature monitor inclusion is embedded within the software's pick-and-pack workflow, which simplifies temperature monitor use and integration, as well as the use of multiple monitors within single shipments.

Temperature Excursion Management features

- Easily record and cumulate IP excursions
- Assign medication-specific temperature excursion thresholds
- Access an excursion assessment interface for quarantine and adjudication management
- Easily incorporate site-recorded temperature data
- Support excursion tracking with single or multiple temperature monitors
- Integrate with a variety of temperature monitors
- Integrate with RTSM systems

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WHO IS SIGNANT HEALTH?

Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 25 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at **www.signanthealth.com**.