

The Signal

Track & Cumulate Temperature Excursion Data Easily with Signant's New Supplies Solution

In our post-pandemic world following COVID-19 and its many vaccine development and supplies challenges, a renewed focus has been placed on the importance of temperature excursion management (TEM) in the modern clinical trial landscape. As a whole, the pharmaceutical industry is producing more expensive, valuable investigational products (IP) that require closer monitoring to ensure that clinical trial patients are only exposed to drugs or vaccines within known, safe stability conditions, and that product usage is optimized to mitigate waste.

The pandemic also expedited trends of decentralization, further emphasizing the need to collect accurate, cumulative temperature excursion data as supply chain models increasingly pivoted towards direct-to-patient models or other hybrid designs.

Though the bar for TEM standards has risen significantly industry-wide, there are still many challenges that sponsors and study teams face with the current systems in place, such as:

Challenges

- Current TEM processes are fragmented and often involve manual, error-prone paper methods to consolidate data from different sources, with no central storage place.
- Most TEM capabilities are limited to excursions within a single location or shipment and can only track individual legs of an IP's journey to the patient.
- A generic profile is assigned to a whole shipment rather than individually assigned for each specific drug within mixed shipments.
- Late notifications of excursions can create a risk of dispensing IP that are not within known stability ranges to patients.

Has your study team faced any of these hurdles? Read on to learn how Signant's TEM solution can resolve them to optimize your clinical supply chain management.

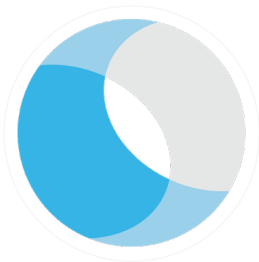
Our solution:

- Facilitates modern management of excursions for all trials in one application.
- Provides a comprehensive record that combines the IP's temperature excursions throughout the whole clinical supply chain.

- Applies generic and medication-specific temperature excursion thresholds to enable sophisticated monitoring within mixed shipments.
- Supports USB or Bluetooth-based temperature monitors so that excursion data can be accessed much earlier via real-time status notifications while the IP is still in transit.
- Integrates with Signant SmartSignals RTSM or third-party apps.
- Prevents IP waste by allowing authorized users to override material status as needed after an excursion assessment, saving costs for sponsors.

At Signant, we've made temperature excursion monitoring easier. Plus, our TEM solution can be integrated with any of our other [clinical supply chain management solutions](#) to optimize your trial from end to end.

Curious to hear more? Download our [TEM brochure here](#) or connect with us to speak with our in-house experts about your protocol.



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 generate quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 20 years, over 400 sponsors and CROs of all sizes – including all of Top 20 pharma – have trusted Signant Health solutions for remote and site-based eCOA, eConsent, IRT, supply chain management, and data quality analytics.