

TSS Clinical Module

Excursion management - from days to seconds

The effective monitoring of temperature throughout the supply chain is of paramount importance in ensuring the safe and protocol-compliant conduct of a clinical trial.

At the same time unpredictable temperature excursions are very common, especially at the later stage of the supply chain. Many are only detected at the clinical site, when it is time to dispense the drug. Each deviation causes the progress of the product along the supply chain to grind to a halt as checks are conducted to make sure it is still suitable to be dispensed.

Patients might have been called in to the hospital to receive their dose, but the visit needs to be cancelled or the patient even sent home without treatment because the clinical site staff didn't get the go ahead to dispense a drug that has shown a temperature excursion.

Data show that the vast majority of excursions were found to fall within the temperature budget in a large clinical trial – products were kept in quarantine in vain – costing the sponsor time, money, excess waste and delays in completing the trial on time.

TSS Clinical Module

The TSS Clinical Module has been developed especially for the pharma industry, and is the result of close collaboration between TSS and Novo Nordisk. It speeds up the investigation process – turning days into seconds, by transforming temperature management into an automated and digitized system.



More stakeholders and higher risk for temperature excursions further down the supply chain

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By comparing aggregated temperature data from in transit and storage loggers with the stability budget on a kit level, the system instantly determines whether the excursion is a deviation or not, allowing proper action to be taken. This is made possible through integration with the RTSM.

If the excursion remains within the stability budget, an automatic release is granted by the system in seconds, and the clinical site staff is informed.

”
We designed the system with TSS, so we know for sure it will be easy to use, because we involved the people who are using it, both the site staff and our own staff. ”

A future-proof solution

The TSS Clinical Module is a technology-agnostic and integration friendly software platform, where the sponsor can decide which in-transit and storage loggers, wireless or passive/USB, to use. It is also integrated to leading RTSM and supports additional future system data feeds. If you would like to implement the TSS Clinical Module, you are not tied to any given technology today – or tomorrow. You will have a future-proof solution that adapts to evolving technologies in temperature monitoring and clinical trial system providers over time.

Key benefits

Patient safety & product effectiveness

Reduce risk of dispensing temperature affected product

Compliance

Automatic, safe storage of data in cloud application, throughout the trial

Sustainability

Reduce need of extra shipments, minimize wasted products

Sponsor attractiveness

Reduced failed patient visits - keep patients enrolled and treatments to schedules