

Temp**EZ**Site Storage Compliance Management Module

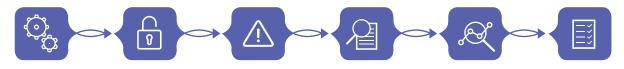
At Almac, we understand that sponsors face a large number of challenges when being tasked with management of temperature data at the clinical site. The complexities of these challenges can range from dealing with manual logs that are time consuming to review, to avoiding the potential for duplication of work when reviewing temperature logs for the same site across multiple protocols.





Site Compliance Process Flow

Almac has designed the Site Storage Compliance module within our temperature management platform TempEZ™ to support sponsors, CROs and CRAs. The functionality facilitates the management of site temperature data in a more automated, streamlined and efficient manner. The Almac Temperature Services team is also available to support sponsors and CROs directly with managing site storage compliance.



Almac completes setup of clinical sites on TempEZ, including linking sites participating in multiple protocols for the same sponsor Access given to relevant CRO and/or sponsor contact Alerts sent to the clinical site to prompt the return of site temperature data – one upload will be linked to all relevant protocols Individual responsible for reviewing the information reported by the clinical site can do so via TempEZ Queries against submitted information can be raised directly from the TempEZ platform

Compliance of sites can be analysed and reported - sites ranked Red/Amber/Green by their level of compliance

Centralising the Management of Site Storage Temperature Data Using TempEZ

Finding the balance between getting the right information centralised for the sponsor and ensuring site compliance without burdening the clinical site or the CRA teams can be a difficult task to get right. When we also factor in the financial implications on the sponsor if there are inefficiencies in collecting temperature data, there are many variables to consider when implementing an effective process.



Centralisation

- · All site temperature data centralised in one location
- Information is easily accessible to the sponsor and CRO reducing time needed to spend on site
- Temperature data is pro-actively collected throughout the study
- Using the Almac supplied site temperature device means one monitor can be utilised per refrigerator/freezer/room at site
- Compliance with Data Integrity and eTMF guidelines



Automation

- Temperature data from one site can be linked to multiple protocols
- Temperature site devices will raise excursions upon upload when alarmed
- Tracking mechanism for the initial shipment and re-supply of site storage devices
- Sites can be queried directly from the TempEZ system consolidating communication
- CRAs/sponsor have the ability to resolve temperature issues remotely prior to site monitor visits
- Sites ranked automatically and assigned a colour (red/amber/green) based on compliance level allowing a risk based monitoring approach to be implemented

Regulatory Compliance



Flexibility

- Data is collected in any format that the clinical site is currently using (USB devices, manual logs, etc.)
- No requirement to download software
- · Additional modules can be activated in the software
- \bullet Excursion Adjudication \bullet Lifecycle Management \bullet Transit Compliance