



Partnering to Advance Human Health

With you for the journey™

Next Generation Temperature Management Solutions



TempEZ™ The Foundation of your Complete Temperature Management Solution

Almac designed the innovative temperature management software TempEZ to ensure complete visibility of your drug's temperature journey throughout the supply chain. TempEZ offers clients a single database to store temperature data from product manufacture to patient administration.

Retaining and analysing temperature information through TempEZ aids in compliance with Good Distribution Practices (GDP) and Data Integrity regulations and helps ensure product quality and patient safety.

How does TempEZ enhance Temperature Management processes within your organisation?



Centralisation

- Transit and site temperature data is centrally stored and readily available for review and analysis
- A complete temperature history proving product has been stored within the label claim to meet regulatory requirements
- Data can be queried and reporting is available for compliance and clinical site performance
- Temperature data stored in line with Data Integrity regulations



Automation

- Transfer of original temperature data into TempEZ directly from the temperature device
- Reduced burden on clinical sites
- No requirement to download and email pdf records
- Temperature device status automatically updates in TempEZ
- Reports automatically generated for review and analysis

Regulatory Compliance



Flexibility

- Range of different temperature device brands compatible for upload to TempEZ
- Temperature data can be collected from any stakeholder
- TempEZ can be utilised for the commercial or clinical supply chain
- Third party distribution partners can register shipments on TempEZ
- No requirement to download software

Almac understands the complex nature of transporting temperature sensitive drugs globally. We have developed our TempEZ™ software platform and Temperature Services offering with these challenges in mind. Our comprehensive temperature management portfolio gives clients the tools and support to implement efficient solutions to manage temperature data throughout the entire supply chain.



Almac's Portfolio of Temperature Services

Compliance Management Service

The Compliance modules in TempEZ provides a tool for sponsors and CROs to collect and report transit and storage temperature data from the clinical site. Combining transit and site temperature data builds a complete temperature history for your product and proves the product has been stored within the label claim.

Transit Monitor Compliance

- Non-compliant sites receive alerts to remind them to upload their transit temperature devices to TempEZ
- Utilising the Almac Temperature Services team to perform this service achieves an average upload rate of 97%
- Protocol specific alerts can be customised and sent out at defined time intervals
- Alerts can include CRO and/or sponsor
- Compliance data can be provided to help CRAs with site monitoring report, close out visits, regulatory submissions and inspections

Site Storage Compliance

- Site storage temperature data can be uploaded into TempEZ via multiple formats (e.g manual logs or temperature devices)
- Temperature data can be reviewed online remotely by the CRO and/or sponsor
- Monthly storage logs, storage excursions and site queries are combined onto one page for easy viewing
- E-signature workflows and audit trails to document the approval of the data for each month
- Sponsor/CRO can prove the drug has been stored within the label claim and manage the compliance of reporting excursions via TempEZ. The Almac Temperature Services team can provide operational support

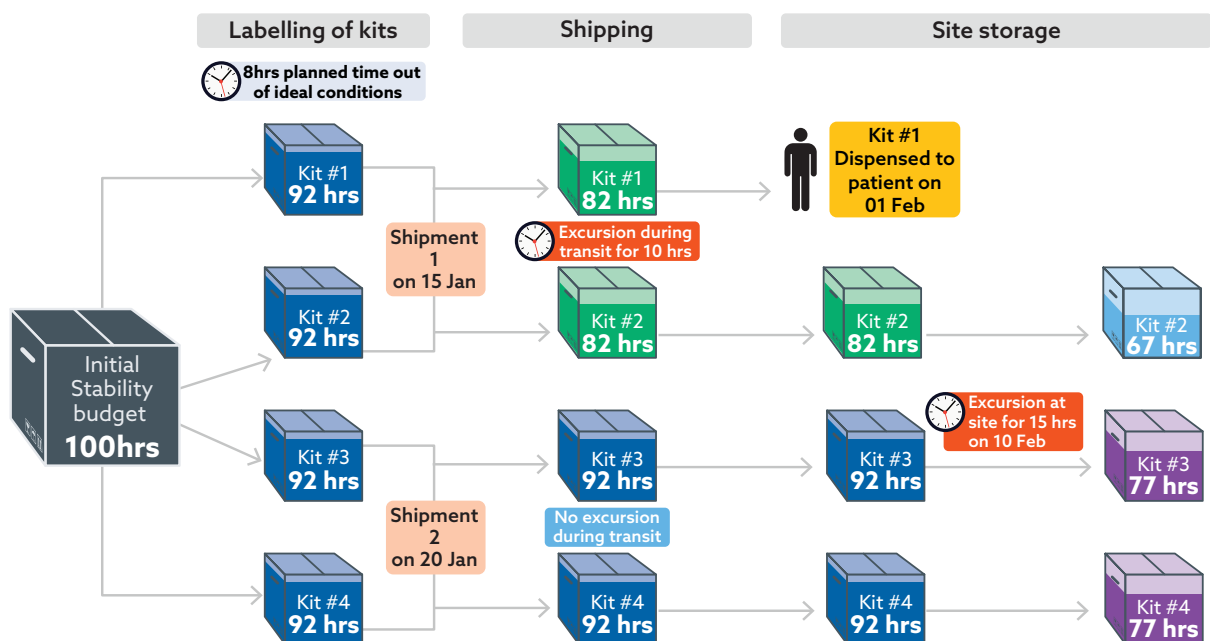


Excursion Adjudication Service

Managing temperature excursions is key to ensuring suitable drugs are administered to patients in a safe and timely manner. Clients can access the TempEZ platform to adjudicate excursions or utilise the Almac Temperature Services team for operational support.

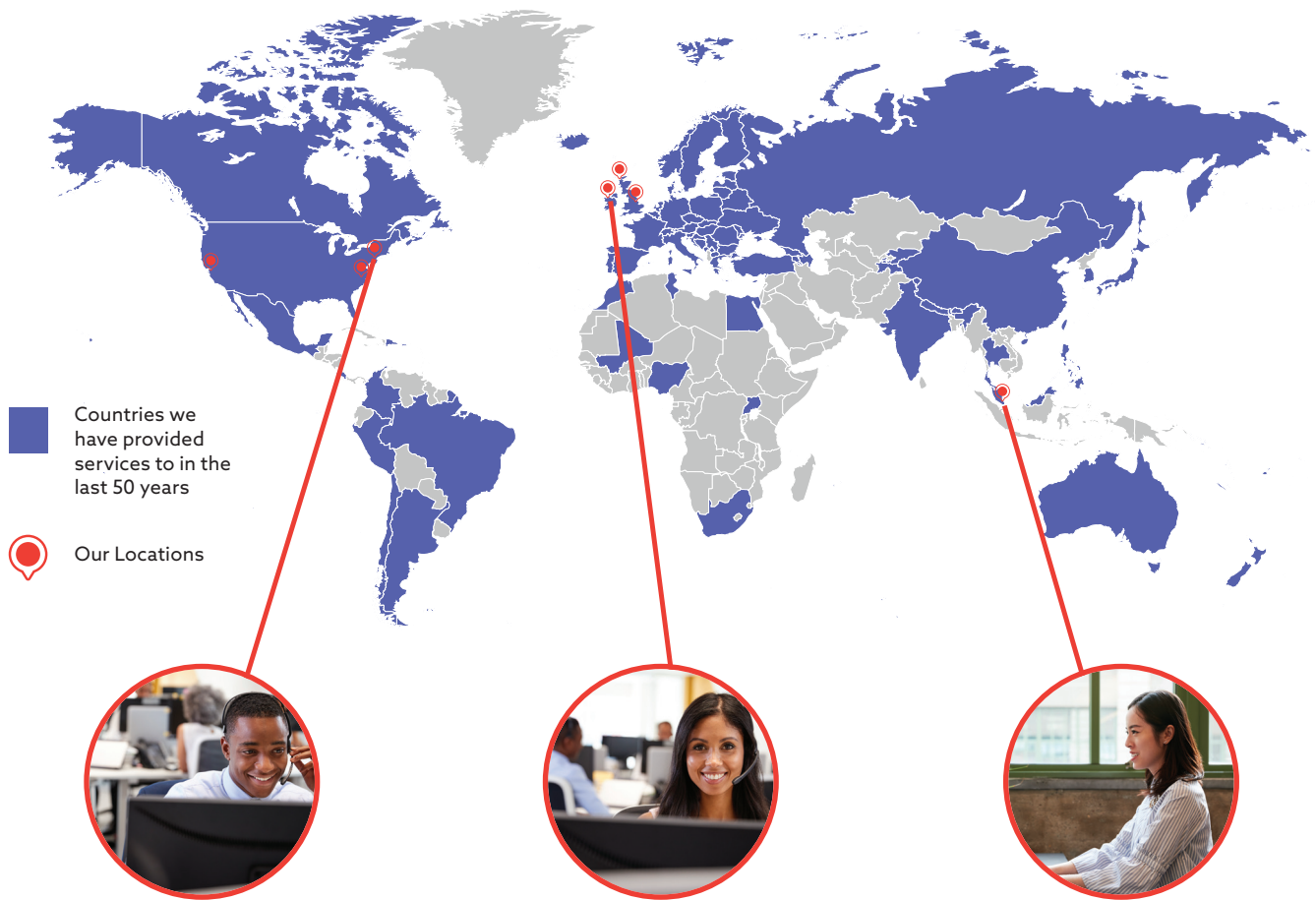
- Notifications are sent automatically from TempEZ to the decision maker when an alarmed transit temperature device or site storage excursion is uploaded
- A unique record is raised in TempEZ where Almac or the client will make the decision
- Users with appropriate access can make decisions on TempEZ and an e-signature is required to complete the approval process ensuring integrity of the data
- An email is automatically sent back to the clinical site when the excursion record is closed in the system, notifying the clinical site of the outcome of the adjudication
- All changes to the excursion status are tracked in an audit trail compliant with Data Integrity regulations

Lifecycle Management Service



If your drug has a cumulative stability budget, a maximum number of freeze/thaw events or a maximum number of excursion events in a temperature range, the Almac Temperature Services team can track these instances using our Lifecycle Management Service.

Time out of conditions, both planned and unplanned, can be tracked at a lot or med ID level with the Almac team making the final decision on whether the drug is safe to administer to patients, in line with the client supplied stability data.



Almac Temperature Services Team – A Global Support Network

The Almac Temperature Services team is a dedicated department to support the setup and delivery of your Temperature Services.

As a global team, governed by global processes, we can provide:

- 24 hour coverage through the combination of our UK, US and Singapore facilities
- An experienced team with access to further knowledge within the Almac Quality department
- Decisions on transit and site storage excursions within 24 hours
- Analysis and reporting on the compliance of clinical sites with uploading transit and site storage temperature data
- Assist CRO and Sponsor oversight requirements with managing temperature data at clinical sites
- Full Lifecycle temperature tracking of your product from receipt at the manufacturing facility to dispensing at the clinical site

Get in touch

UK

Almac Group
 (Global Headquarters)
 9 Charlestown Road
 Seagoe Industrial Estate
 Craigavon
 BT63 5PW

clinicalservices@almacgroup.com
 +44 28 3836 2436

US

Almac Group
 25 Fretz Road
 Souderton PA18964
 United States of America

clinicalservices@almacgroup.com
 +1 (215) 660 8500

Asia Pacific

Almac Pharmaceutical
 Services Pte. Ltd.
 9 Changi South Street 3
 Unit 01-01
 Singapore 486361

clinicalservices@almacgroup.com
 +65 63090720