From Depot to Dose:

The Power of RTSM Integration in Temperature Excursion Management

Presentation by Endpoint Clinical

Featuring Berlinger

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Joanna Tait

Solutions Consultant

Dr. Anne Stolle

Key Account Manager
EMEA

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Agenda

1. Temperature Monitoring At-a-Glance
2. Real-World Use Cases
3. Depot-to-Site Logistics
4. Site Support
5. Why Integration Matters

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Monitoring for Clinical Supply Chains

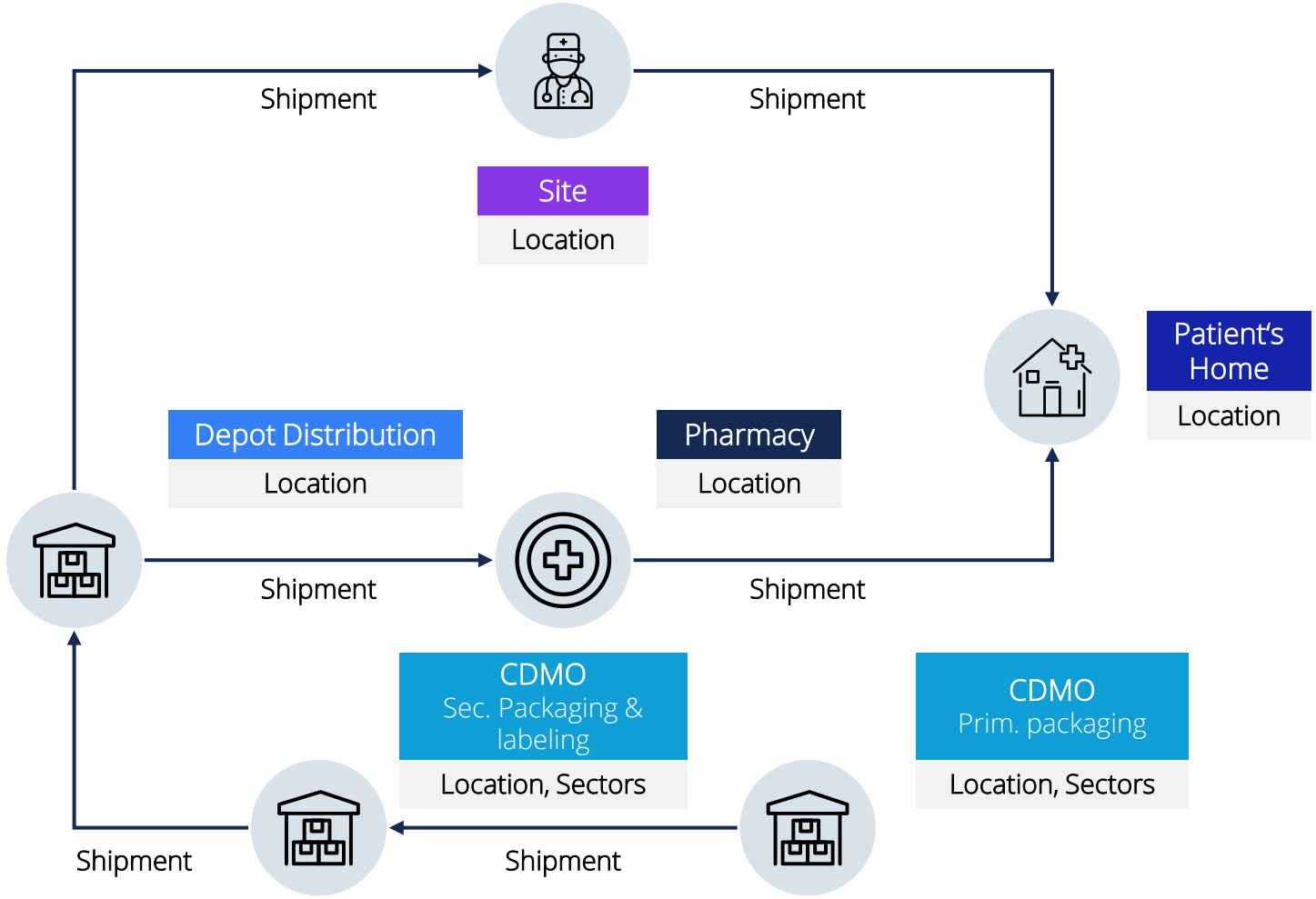
Importance of Temperature Monitoring:

Temperature excursions can degrade product integrity, impact patient safety, and create compliance risks.

Minor deviations cause costly delays and wasted inventory.

Real-time monitoring solutions like SmartView detect excursions in real-time, triggering immediate action.

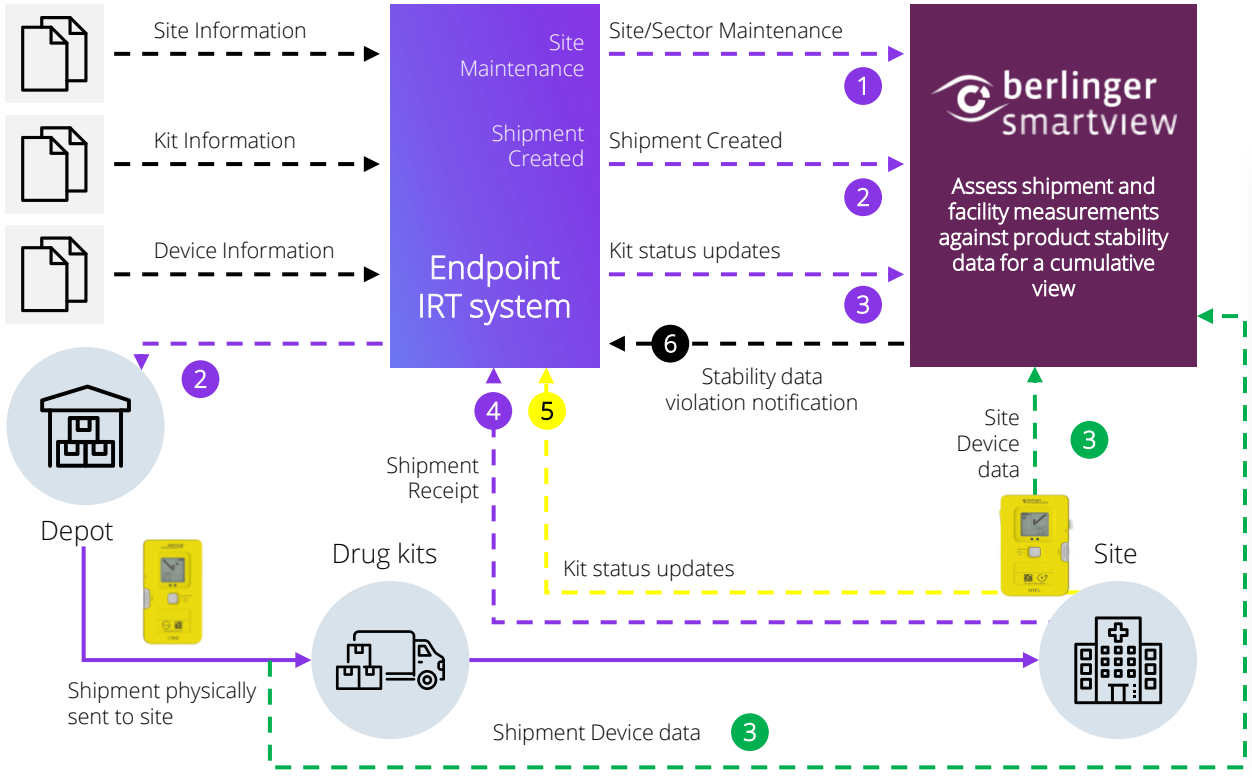
Endpoint Clinical's RTSM system automates tracking and ensures sites are always stocked with viable products.



Endpoint SENSITECH berlinger

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

End-to-End Monitoring: One Platform, Full Control



Temperature Controlled Item: Follow the Drug-Kit as a digital twin

RTSM enables proactive decision-making by integrating shipment and site data.

By aligning temperature tracking with inventory management, clinical teams gain full control over supply chain logistics.

This integration leads to faster response times and better regulatory compliance.

Endpoint SENSITECH berlinger

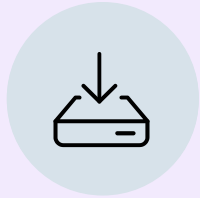
Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Seamless Integration, Real Results

Significant time and workload savings for CDMOs, CROs, Sites and Sponsor

Avoidance of expedited Shipments, Patient Rescheduling,

Much improved audit preparation; all data in one place



Automation has reduced human errors for all stakeholders

Greatly reduce manual processes, few or no manual assessments

Improved Patient Safety results from automation and single source of truth

Much reduced risk of dispensing drug that is no fit for use

Reduced material wastage of IMP/ drug kits

Lanes with a high percentage of Excursions can be evaluated and issue resolved: that way future waste can be avoided

Endpoint SENSITECH berlinger

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Ongoing Innovation

Further improving visibility

RTSM Connectivity

Utilization of next generation temperature loggers capable of:

- Providing auto-resolution of TEs capability through an integration with RTSM
- Stability budget management through RTSM integration
- Hub and Spoke Models

Loggers

Sensor options:

- Temperature
- Humidity
- Light
- Tilt
- Shock
- Free-fall

Data transmission:

- NB-IoT
- Wi-Fi
- BLE
- Cell LTE Cat M1 (4G/5G)
- 2G

Cloud-Based

Remotely configurable tracking technology provides insights to:

- Shipping conditions
- Handling
- Risk excursion (prediction)
- General status beyond the oversight of drug supply stakeholders

GPS Real-time

Use of monitoring devices capable of real-time communication of:

- Location status in real-time
- Notifications and alerts

Endpoint SENSITECH berlinger

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Real-World Use Cases for RTSM-Integrated Temperature Monitoring

Endpoint

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Use Case 1: IMP with short shelf-life & -80°C requirement

Challenges Beyond Temperature Management Alone

Real-time:

know where the IMPs are and in what condition in

real-time

Temperature:

Non-radionuclide part of the IMP is highly temperature sensitive

Location:

The radionuclide has a short half-life. Disruption or delay in the transport process will jeopardize the integrity of the IMP

Light

the inclusion of a light sensor serves as an additional safeguard.

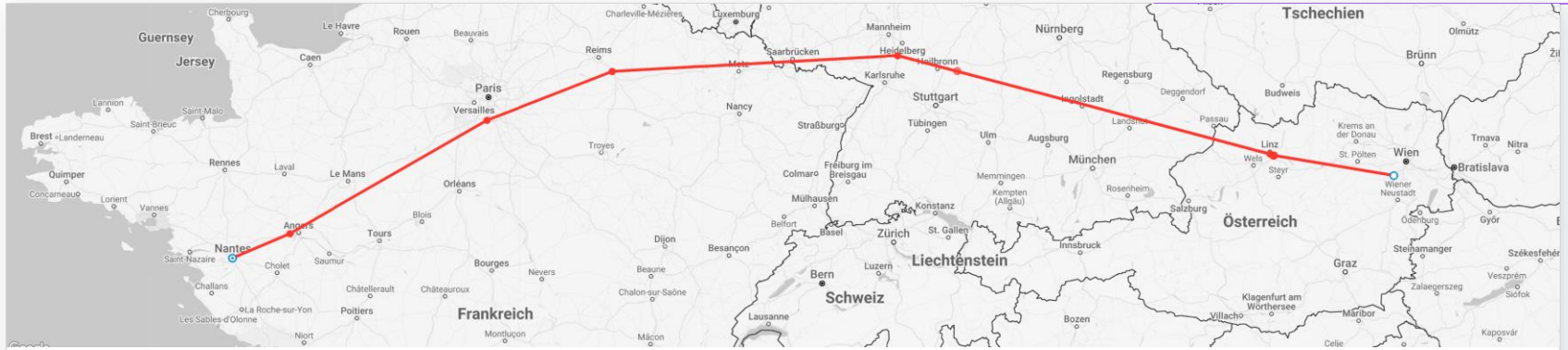
Tilt:

Some solutions for shipping materials at approximately -80°C require them to be maintained in an upright position

Endpoint SENSITECH berlinger

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Real-Time Monitoring with SmartSystem

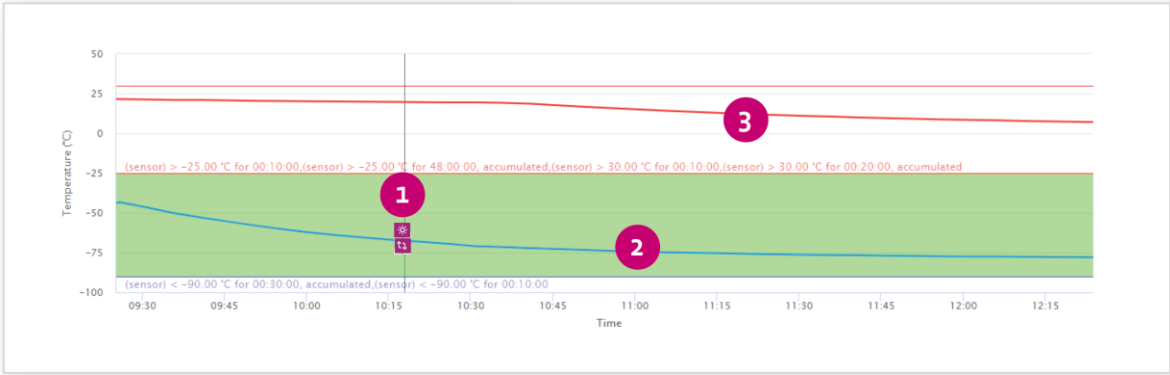


GPS

location of events during shipment from Production to clinical site

Temperature:
both inside and outside packaging (2) and (3)

Tilt and light:
opening of package (1)



Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Use Case 2: Shipment Monitoring

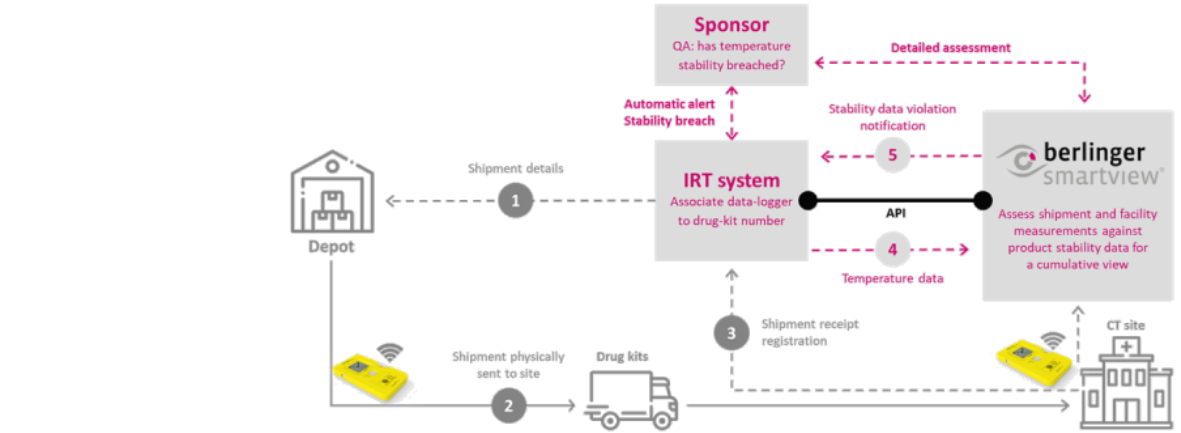
Direct Administrative Savings of an End-to-End IRT/SmartView Integrated System

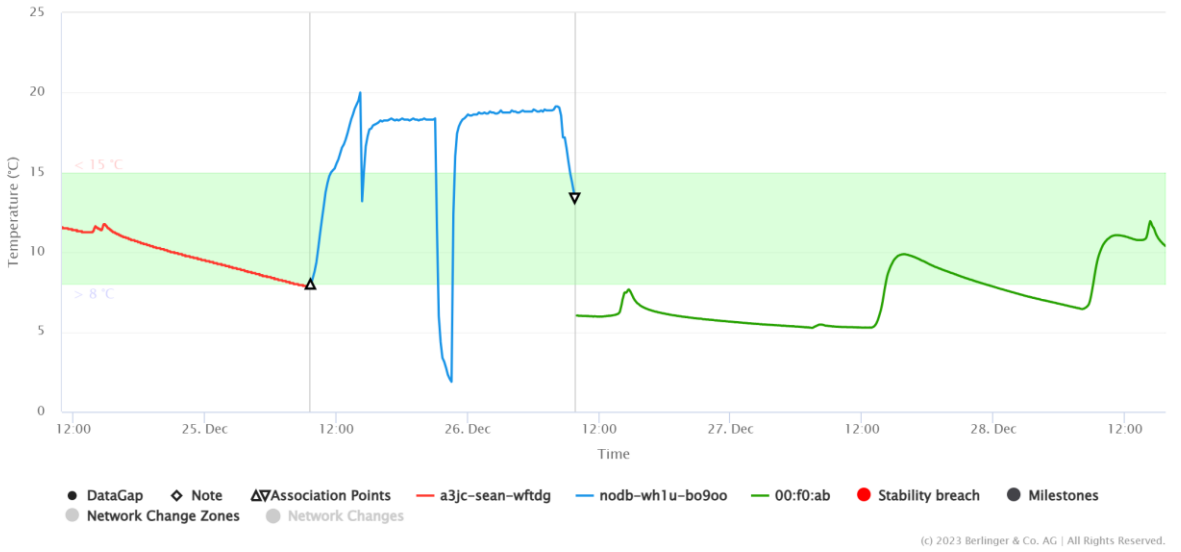
The Case:

- A sponsor working with a CRO and a CDMO
- The study: Ph II; IMP: monoclonal antibody
- Over 1800 depot-to-site shipments
- 4 depots; 89 sites; 90 unique legs
- Period: 2 years
- 110 temperature excursions over 79 shipments
- TE duration: 2 – 8386 mins (median = 17 mins)
- 21 shipments experienced a stability budget breach

Administrative savings of an integrated solution on shipments :

- **Before:** Manual/Paper Based/Email
- **After:** Integrated Solution





(c) 2023 Berlinger & Co. AG | All Rights Reserved.

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Use Case 2: Shipment Monitoring

Direct Administrative Savings of an End-to-End IRT/SmartView Integrated System

TE Process Before

For each Temp Excursion:

- Manual filling out form/info by site
- CMO review if appropriate
- Responsible person review
- Consultation of many sources for temp info and prior TEs
- Site putting IMP kits in quarantine
- QA / CDMO forwarding info to site
- Info entered into IRT
- Site marks IMP kits for destruction or made available again

110 TEs needed to be assessed

21 stability budget breaches to be assessed

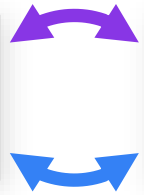
Total time spent/cost: 702 h, ~120'500 €

TE Process After Integrated System

TE without budget breach: "auto-resolved": no time needed

21 stability budget breaches to be assessed

Total time spent/ cost: 21 h, 6'400 €

Endpoint  berlinger smartview

Endpoint SENSITECH berlinger

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

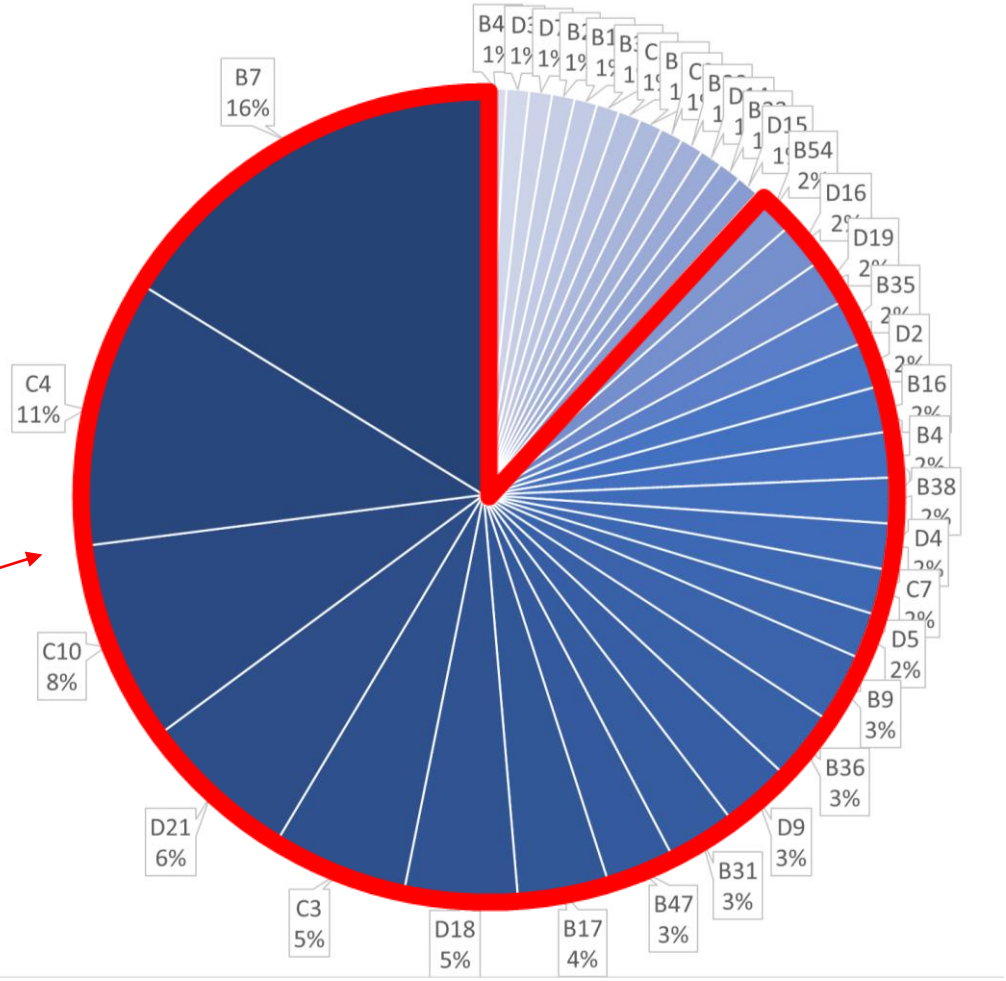
Use Case 2: Shipment Monitoring

An Opportunity to Improve

Analysis of Depot-to-Site

- Over 1800 shipments
- 79 shipments where 1 or more excursions occurred
- Most of the temperature excursions happened in legs B7 (16%) and C4 (11%) and have led to stability budget breaches
- Opportunity to further delve into “risky” legs and improve: lane assessment

These Depot-Site shipments have led to full stability budget breaches



Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Streamlining Depot-to-Site Logistics for Efficiency and Accuracy

Endpoint

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Real-Time Shipment Monitoring Automation

Endpoint

berlinger smartview

A Shipment is created

A Device is assigned to the Shipment

The Shipment is under way

A Product Stability Breach is caused in The Shipment

A decision is made on the status of a kit that has been Quarantined for the shipment

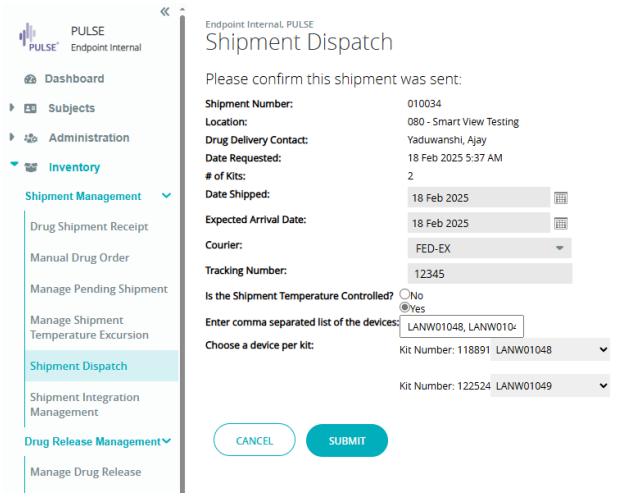
The status of a kit is updated

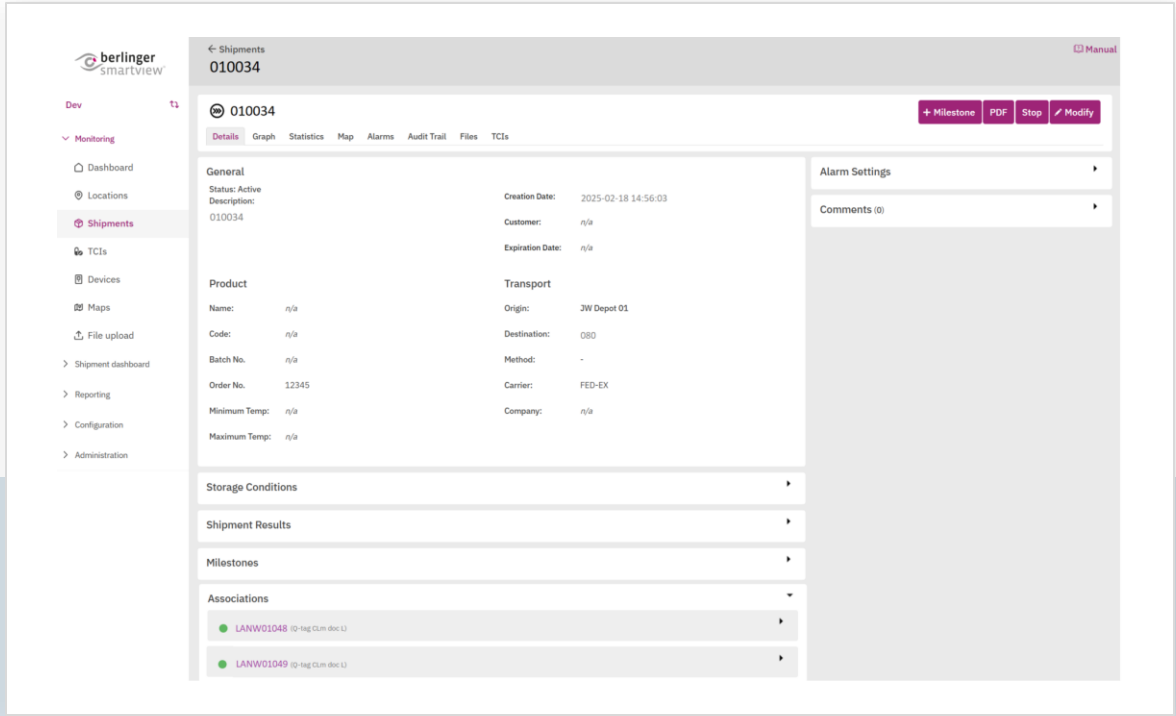
Endpoint SENSITECH berlinger

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

RTSM Shipment Creation

Within IRT, Shipments are raised and dispatched. Each Kit is assigned a device which monitors the kit's status.

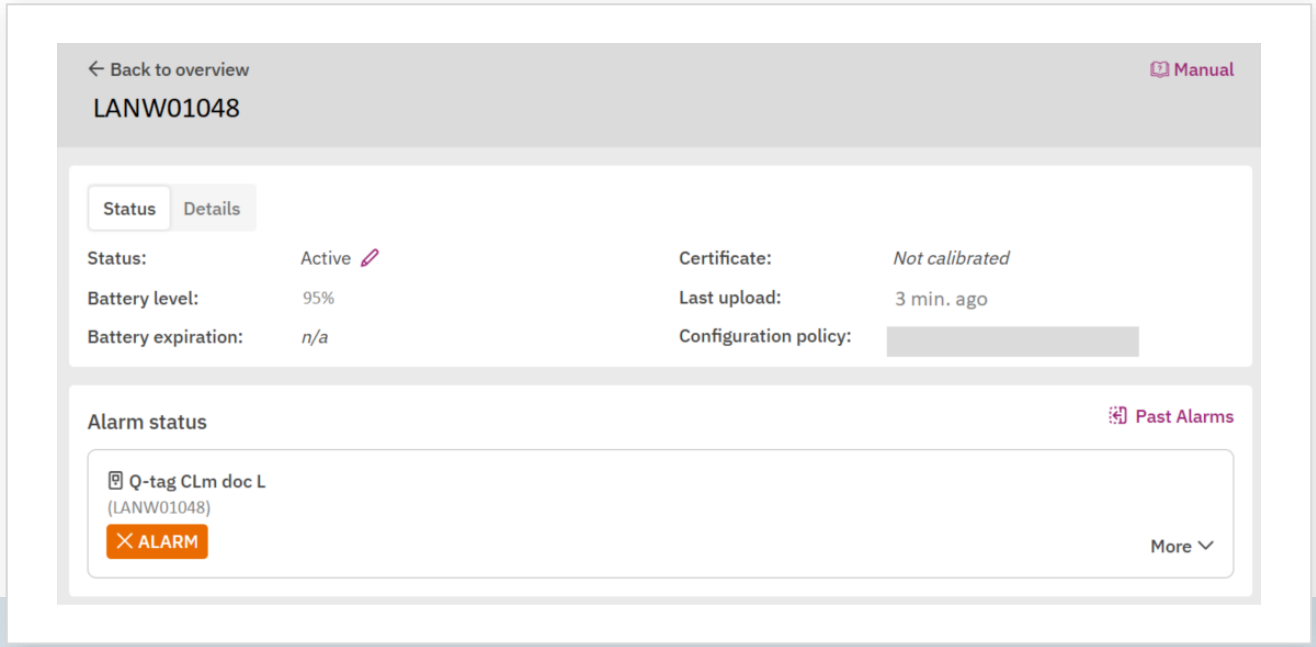




Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Product Stability Breach

berlinger smartview



Once kits and shipment are within SmartView they are monitored via the device associated.

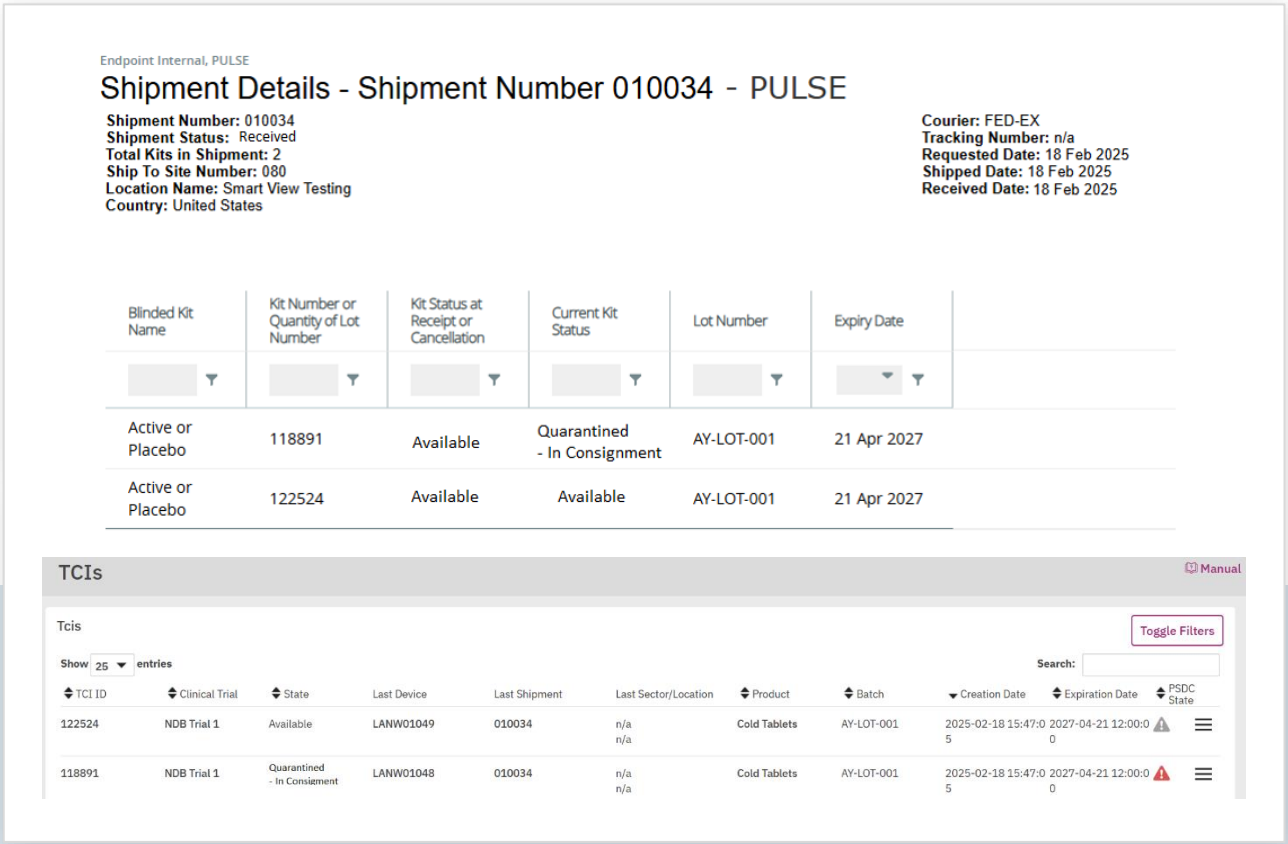
If the device records a discrepancy according the stability rule configured per drug type an **alert will be sent to IRT** to inform of a breach.

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Breach Response in RTSM

If SmartView detects a Stability Budget Breach, i.e. the device reports the temperature is out of set range for a certain period of time an alert is sent to IRT.

IRT will determine which kits are associated to the triggered device, whether it is a shipment or a sector and will update each kit accordingly. This status is then sent back to SmartView keeping both systems aligned.



Endpoint Internal, PULSE

Shipment Details - Shipment Number 010034 - PULSE

Shipment Number: 010034
Shipment Status: Received
Total Kits in Shipment: 2
Ship To Site Number: 080
Location Name: Smart View Testing
Country: United States

Courier: FED-EX
Tracking Number: n/a
Requested Date: 18 Feb 2025
Shipped Date: 18 Feb 2025
Received Date: 18 Feb 2025

Blinded Kit Name	Kit Number or Quantity of Lot Number	Kit Status at Receipt or Cancellation	Current Kit Status	Lot Number	Expiry Date
Active or Placebo	118891	Available	Quarantined - In Consignment	AY-LOT-001	21 Apr 2027
Active or Placebo	122524	Available	Available	AY-LOT-001	21 Apr 2027

TCIs — Manual

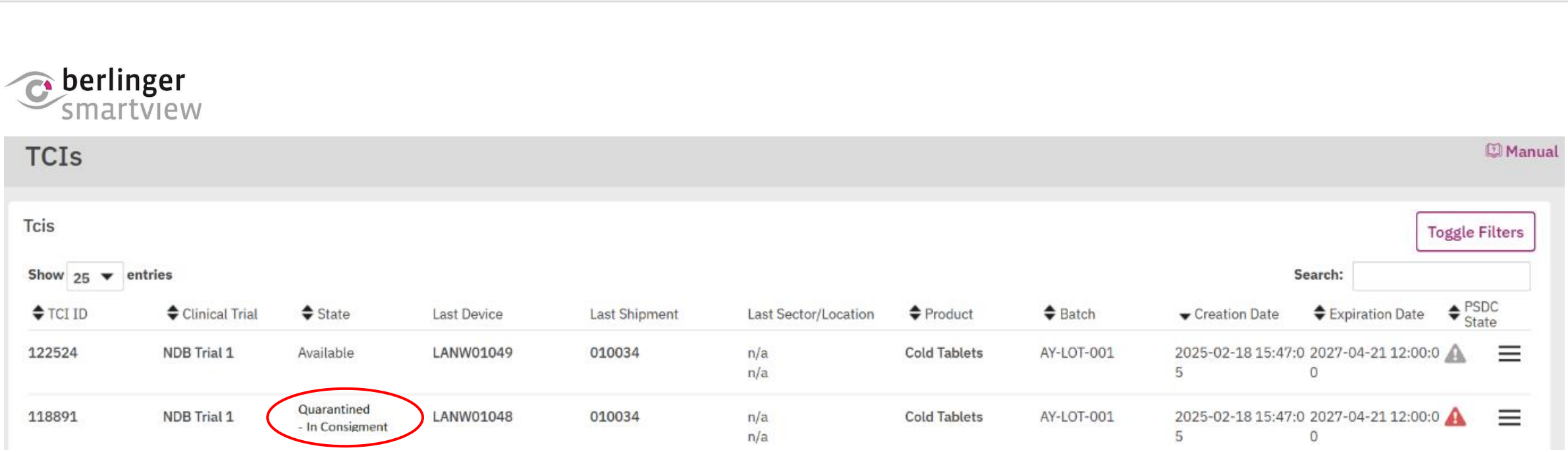
Tcis — Toggle Filters

Show 25 entries — Search:

TCI ID	Clinical Trial	State	Last Device	Last Shipment	Last Sector/Location	Product	Batch	Creation Date	Expiration Date	PSDC State
122524	NDB Trial 1	Available	LANW01049	010034	n/a n/a	Cold Tablets	AY-LOT-001	2025-02-18 15:47:05	2027-04-21 12:00:00	
118891	NDB Trial 1	Quarantined - In Consignment	LANW01048	010034	n/a n/a	Cold Tablets	AY-LOT-001	2025-02-18 15:47:05	2027-04-21 12:00:00	

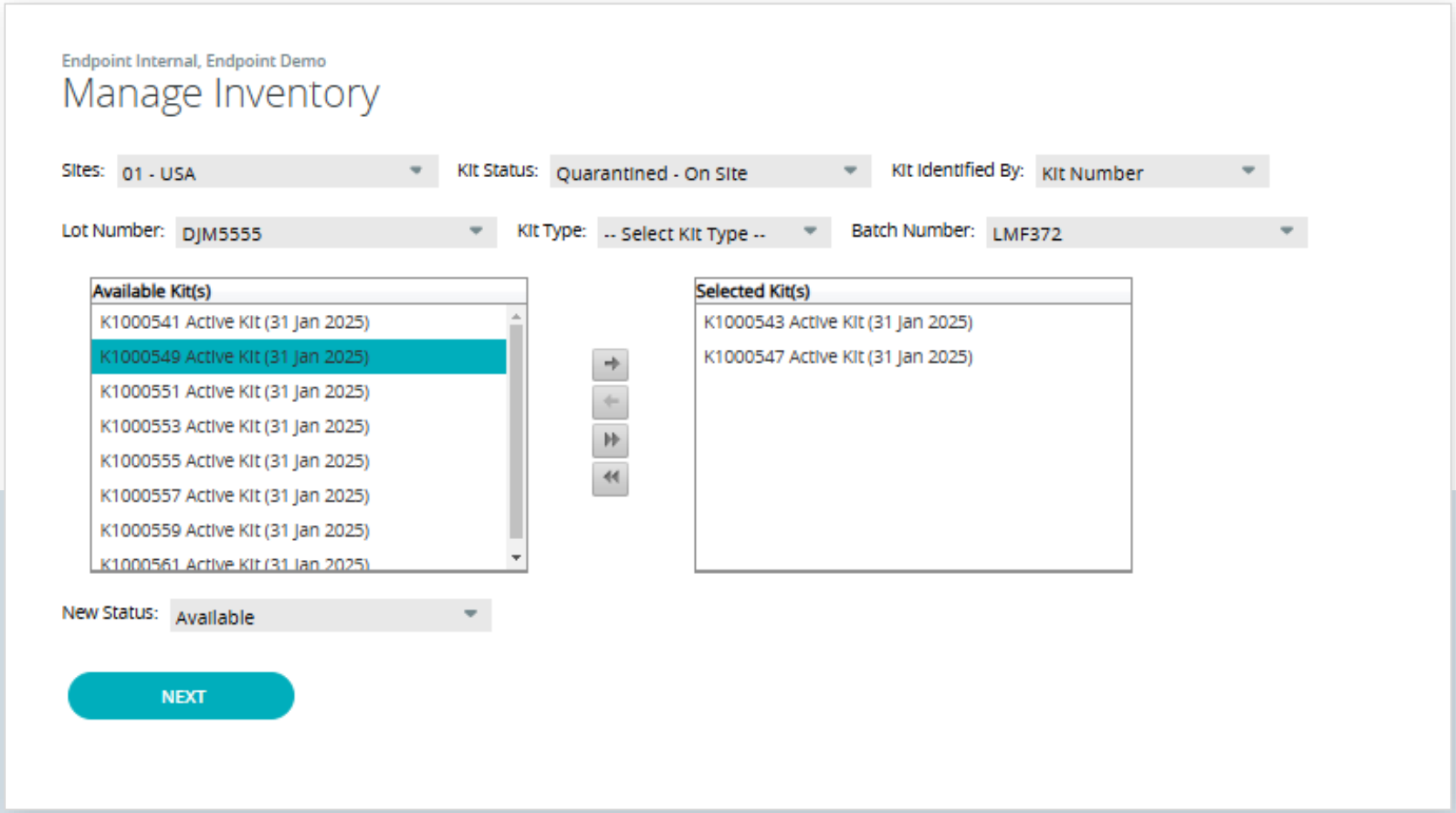
Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

SmartView Alerts and Quarantine Management



Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Quarantined Status Assessment in RTSM



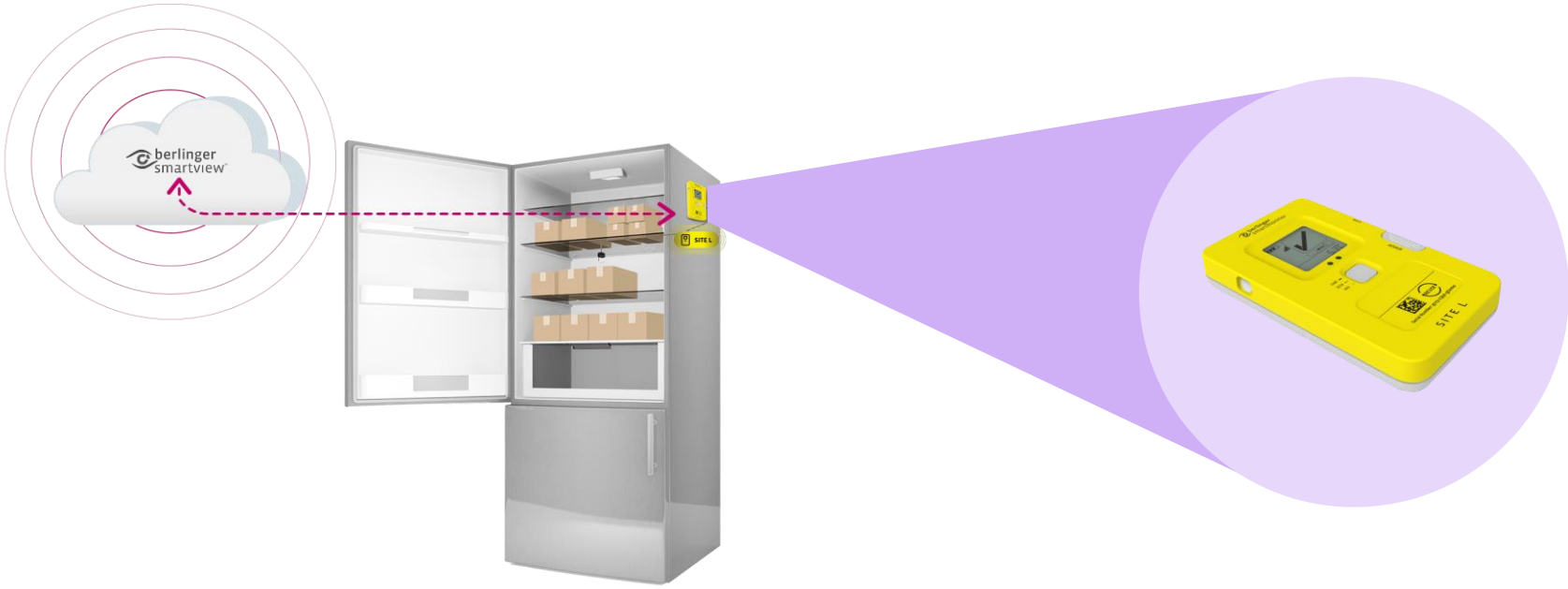
Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Supporting Sites, Improving Patient Access, Reducing Errors

Endpoint

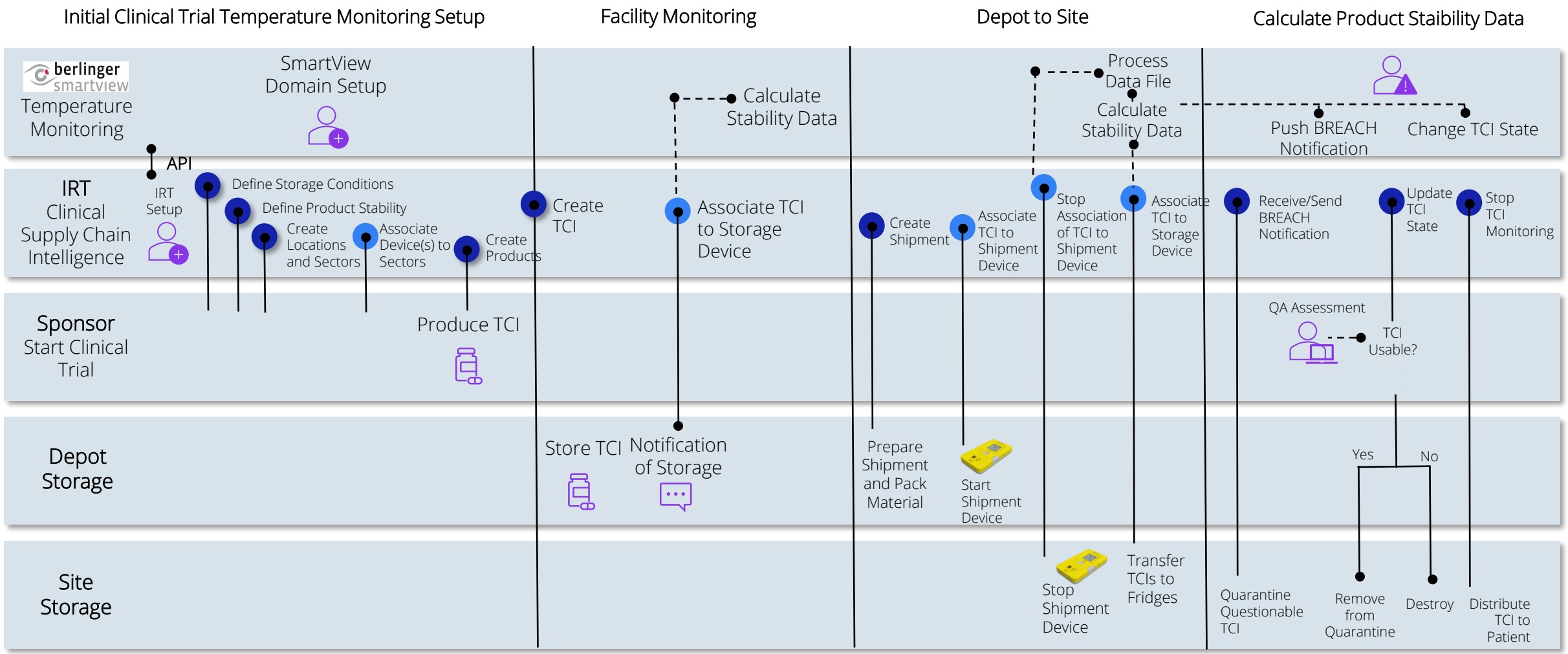
Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Temperature Readings On Site



Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Clinical Trial Temperature Monitoring Process



Endpoint SENSITECH berlinger

Created/Associated via IRT Associate Berlinger Temperature Monitoring Devices

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Conclusions

Seamless RTSM & SmartView integration **ensures clinical sites maintain continuous access** to temperature-sensitive treatments.

By automating monitoring, response, and resupply, RTSM **minimizes human error, enhances compliance, and reduces wastage.**

Sponsors benefit from **improved efficiency, reduced operational burdens**, and strengthened **trial integrity.**

The future of clinical supply management is in **real-time, data-driven decision-making**—empowered by RTSM and SmartView.

By reducing manual interventions, optimizing resupply, and preventing unnecessary drug wastage, RTSM delivers **significant cost savings for sponsors and sites** alike.

Endpoint SENSITECH berlinger

Copyright © 2025 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.

Thank you.

Endpoint

SENSITECH & berlinger

Visit Endpoint at booth 42 and Berlinger at booth 44

Copyright © 2024 Endpoint. All rights reserved. Proprietary & confidential - not for distribution.