



White paper · Clinical trial supply

Preventing costly delays in clinical trials via real- time shipment tracking

How real-time visibility of investigational product protects
participant visits, study timelines and market exclusivity.

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Executive summary

In clinical supply, a late kit is a missed visit.

Most of what makes a clinical trial long cannot be shortened. But many of the most common delays can, and they often start in the supply chain. Real-time monitoring of investigational medicinal products (IMP) helps save lives, time and money, and reduce waste.

80%

of clinical trials are delayed by at least one month

\$18_M

starting cost of a one-month delay for a typical drug

\$200_{M+}

potential lost revenue from 30 days' delay for an expensive drug

3–6_{mo}

longer than planned for many delayed Phase III trials

Key takeaways

- Temperature excursions found after arrival cancel participant visits and trigger protocol deviations.
- Real-time monitoring lets teams intervene en route, before IMP reaches the site.
- Integration with RTSM and eTMF multiplies the value through automation.
- Reusable devices make the clinical supply chain naturally circular.

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01

Clinical supply chain challenges

With 80% of clinical trials delayed by at least one month, optimizing a clinical trial timeline is a complex challenge regardless of scale. Patient health outcomes are at stake, as well as millions of dollars in lost market exclusivity.

Real-time monitoring of IMP shipments helps solve this challenge. It helps ensure the right participant safety and efficacy data is generated while minimizing time to market. Pharma and biotech companies can use real-time visibility of clinical supplies to sites, and the automation it unlocks, to avoid many of the delays that threaten to derail study planning.

Scaling up to global Phase III studies at hundreds of thousands of sites, each with unique challenges, requires multi-billion-dollar investment. Participant safety is the top priority, but return on investment is vital too.

Recruitment and retention is the main reason so many trials face delays. Without end-to-end visibility of IMP availability and quality status, study managers can't plan participant visits with certainty.

Until stability data is established, IMP is often shipped in over-engineered packaging at conservative ranges. Combined with small batches and randomization packaging, one damaged package has a costly knock-on effect, amplified by sensitive new cell and gene therapies.

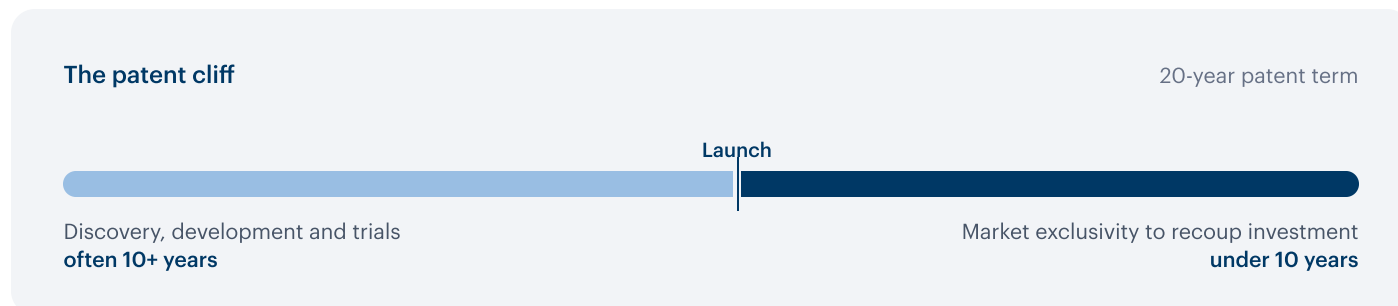
“ There are countless points at which the agility, efficiency and reliability of the supply chain will influence whether a clinical trial stays on track. Given this scale, small improvements quickly add up to enormous benefits.

Alison Riggott · Director of Clinical Solutions

02

The implications of delay

Every week a new drug isn't on the shelf can cost millions in lost sales, and for patients waiting on it, the health cost can be life changing.



Of the 80% of Phase III trials that face preventable delays of at least a month, many take 3–6 months longer than planned. On a conservative estimate of lost post-launch exclusivity, a month's delay for a typical drug starts at around \$18 million. For expensive drugs, 30 days could cost more than \$200 million.

Exclusivity matters because of the patent cliff. Reaching marketing authorization often takes more than a decade and costs billions, and the clock on return starts when the candidate is first identified.

A pharma patent lasts 20 years. When development takes more than 10, less than 10 remain to recoup the investment before generics reach the shelves. The steep drop in profit when protection ends gives the patent cliff its name.

That expiry keeps treatment affordable and the pipeline moving. For pharma companies, it means time is of the essence.



The combined pressure from prescribers anticipating a new drug and shareholders looking for a return before the patent expires must be balanced with the time needed for an adequate safety profile. This adds value to any solution that mitigates delays.

Alison Riggott · Director of Clinical Solutions



03

How passive tracking aggravates delays

"If you have participant visits planned for randomization or their next dose, but the IMP can't be administered because a temperature excursion is being investigated, you can't always say, 'Come back tomorrow.'"

Alison Riggott · Director of Clinical Solutions

The clinic may only run once a week, or participants may not be able to return on another day. Excursions have a butterfly effect on clinical trials. When shipment monitoring is passive, these are the areas most often affected:

01 Internal investigation time for the sponsor

03 Rescheduled visits and out-of-window dosing

05 Recruiting replacement participants

07 Discarded product, and its environmental cost

02 Quality paperwork for investigations, and approval

04 Protocol deviations and protocol amendments

06 Strained relationships with investigators

08 Lost access to IMP and delayed release

Recruitment, retention and the protocol

One key complication for recruitment is the distance participants travel, an average of two hours in the US. The longer the distance, the greater the impact of any rescheduling. Decentralized and hybrid trials help address this, and amplify the benefits of real-time monitoring.

If an excursion can be prevented or investigated before the drugs arrive, the benefits include fewer out-of-window visits, deviations, dropouts and product loss, and less burden on sites managing quarantine and rescheduled clinics.

A participant moved from dosing on weeks 4, 8, 12 to weeks 5, 8, 12 can constitute a protocol deviation, shrinking the per-protocol population. Data must stay statistically powered while exposing the fewest possible participants.

Participants lost to follow-up must be replaced, and are still followed for safety, which adds cost and raises ethical questions about unplanned dosing.

The knock-on effect for RTSM and inventory

When a kit's integrity is in doubt, it has to be destroyed and replaced, and in a blinded trial that is rarely simple.

1

Excursion puts a kit in doubt

2

Kit is destroyed from a small, costly batch

3

Blinded, coded replacement is resupplied

4

Or the RTSM is reprogrammed to hold the ratio

Drugs are labelled with randomization codes programmed into the Randomization and Trial Supply Management (RTSM) system, and each site holds a specific allocation of blinded kits. Not replacing a kit means someone must reprogram the trial so the ratio of comparator to IMP matches the randomization scheme. This is the value real-time visibility of IMP can deliver.



04

Preventing delays in real time

Real-time monitoring and process automation keep clinical study timelines and budgets on track, from primary warehouse to point of use.

Real-time devices send immediate alerts on deviations, so teams can act to safeguard the drug. For IMP moving through challenging airports such as Mumbai, seeing a delay at customs before arrival gives the best chance to intervene.

It reduces spoilage and loss, improves sustainability and keeps trials on track.

It's one thing to transport and store product perfectly; regulations demand that you prove it. Storage at site matters as much as transit.

From Johns Hopkins University to a small Guatemalan hospital, sites are expected to offer identical conditions. In reality, they vary widely.

"When a real-time monitoring solution is integrated into the RTSM, there is an opportunity to gain value from the automation this unlocks. If the status report is automated, the pharmacist doesn't need to mark it off, line by line."

Alison Riggott · Director of Clinical Solutions

"Monitoring device technology today includes location tracking for full visibility of shipments. This is a game-changer for clinical trials, enabling you to intervene and avoid delays that can flush a whole trial down the drain."

Ada Pálmadóttir · VP Business Development

Full visibility saves time and money

"Real-time visibility is a key to unlocking automation opportunities that boost efficiency, solving problems that some pharma companies may not even realize they have."

Carsten Lützhøft · CCO

Automating alert notifications removes the burden on sites to report excursions. Sites usually aren't responsible for reporting them, and don't always report them all, but in practice the burden lands on them.

If the sponsor can deal with an excursion en route, it's a big win for sites and for product safety. The delivery report is emailed automatically instead of printed and filed.

Reports can also be filed automatically, so CRAs have instant access instead of asking and waiting. With remote file reviews, their visits go to what can't be digitized, like building relationships with investigators and teams.

Real-time data also streamlines communication across large project teams and improves overall supply chain reliability.



Automated alerts

Excursions reported for the site, not by it



Automatic filing

Delivery reports in the file without printing



Remote review

CRAs see records before they arrive



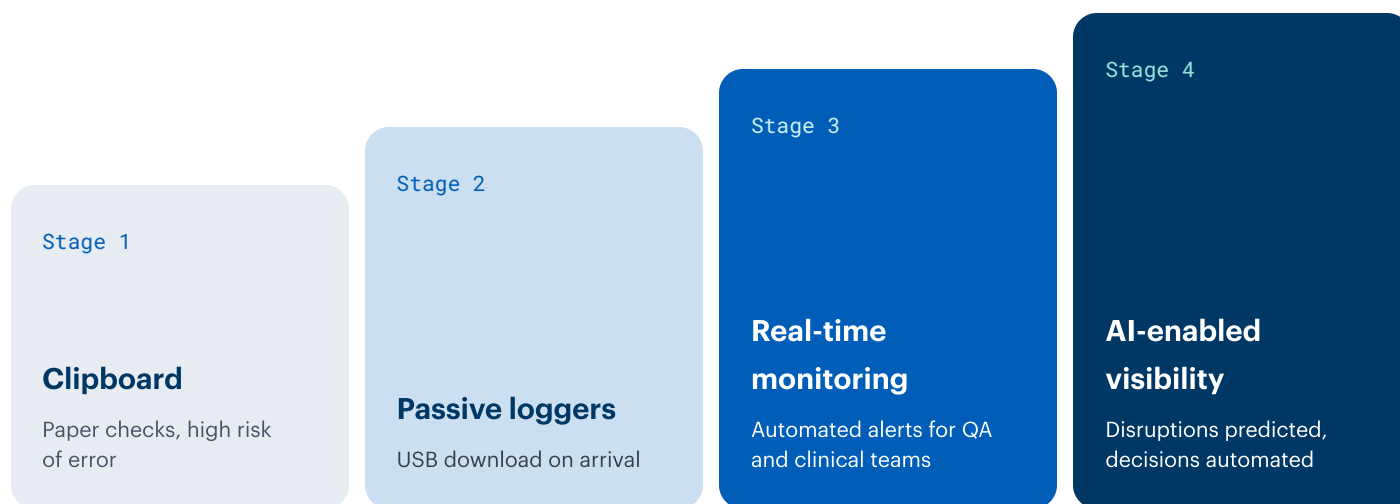
For logistics providers, real-time monitoring makes it possible to manage operations proactively, anticipating and mitigating issues for their pharma customers before they escalate.

Carsten Lützhøft · CCO

05

Compliance at every level of digital maturity

Getting timely temperature data from sites is a common challenge. The pain points depend on where an organization is today.



Some sites still rely on someone with a clipboard. Replacing it with a tablet already modernizes documentation. Electronic site files will be the norm within a few years.

Passive loggers are a step up, but an excursion still starts a chain of emails. One sent on a Friday afternoon might not be opened until Monday.

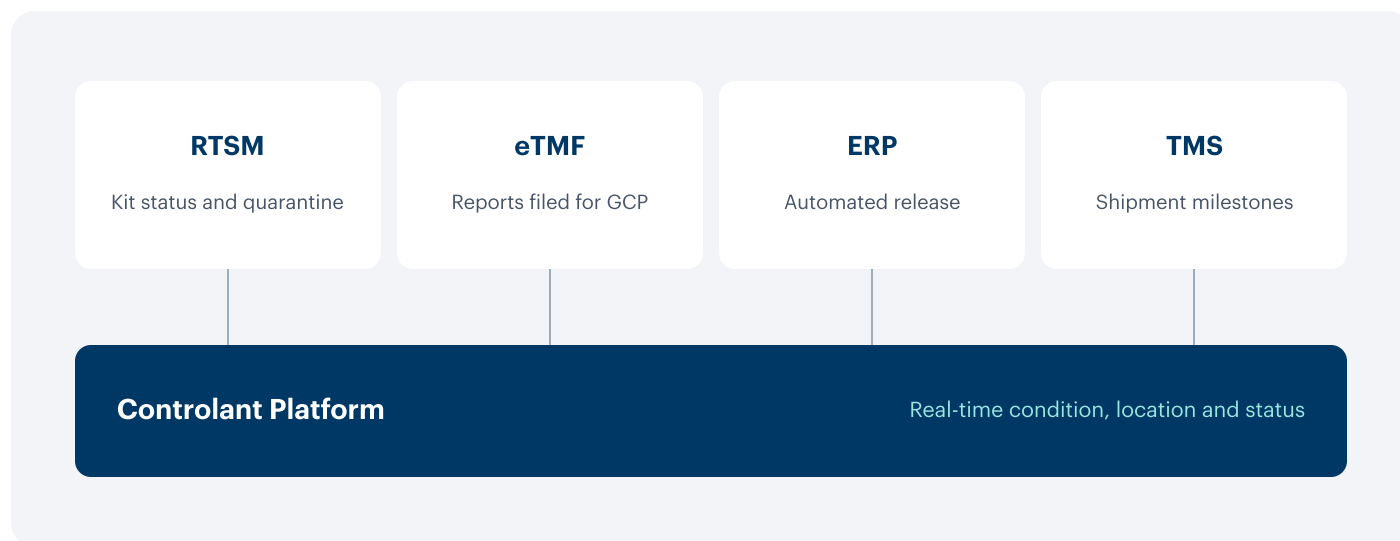
Reconciling data from multiple sources invites human error, and global studies span time zones.

At the most mature stage, device data feeds AI that identifies patterns and predicts disruption, from rerouting shipments to warning sites ahead of a delay.

“ Real-time loggers let clinical management and quality assurance monitor locations and temperatures and receive automated alerts as soon as anything is amiss. Automation boosts the ROI, with project managers no longer managing the data by hand.

Alison Riggott · Director of Clinical Solutions

Integration and automation are value multipliers



Monitoring that integrates with ERP and transportation systems keeps data flowing. In a mature clinical supply chain, real-time monitoring can enable automated product release, cutting manual inspection and release lead times.

Quality reports are generated automatically and accessed through the platform, instead of assembled from files.

Like RTSM, eTMF integration streamlines clinical workflows. The Trial Master File is essential for Good Clinical Practice compliance.

Connecting eTMF to the visibility platform amplifies its benefits: automatic data collection, populated templates, remote collaboration, security and real-time transparency.

“ At clinical sites, real-time visibility makes tasks easier, processes smoother and human error less likely. It helps the pharma company enable site staff to manage their trials more effectively.

Ada Pálmadóttir · VP Business Development



06

A more sustainable future for clinical trials

If healthcare were a country, it would be the fifth largest polluter on Earth, with the pharma supply chain a hefty share. New solutions must be sustainable across the whole chain.

Clinical shipments are small, often in reusable boxes, and repeat the same routes from warehouse to site pharmacy. A circular model is more efficient and sustainable than single-use loggers.

Every dose comes with biological samples to ship to central labs. As devices get smaller, the return trip can monitor those samples too.

Emissions avoided in 2023 with reusable Saga devices

8,203_t

CO₂eq versus single-use loggers

33.8M_{km}

equivalent driving distance in an average fuel-powered car

“ When real-time monitoring devices are reusable, return logistics enable an integrated circular business model, with loggers returned from the receiving site to the primary warehouse.

Vicki Preibisch · VP Sustainability

07

Seven key recommendations

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| 01 | Start with low-risk, high-yield improvements | Phase III is often the best place to start, with the most to gain across many international and varied sites. |
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| 02 | Ensure compliance | Choose pharma-validated technology that complies with 21 CFR Part 11 and EU Annex 11, governed by the necessary SOPs. |
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| 03 | Further sustainability | Reusable devices and return logistics, from a provider with a science-based climate plan and third-party ESG reporting such as EcoVadis and CDP. |
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| 04 | Maximize integration | A platform that integrates with RTSM, eTMF and other systems has more impact and is easier for teams to adopt. |
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| 05 | Automate workflows | Digitize stability profiles to automate product release, and automate report management for pharmacists and site staff. |
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| 06 | Keep it simple and holistic | A GxP-validated, user-friendly platform, with data access for non-account holders at sites with high staff turnover. |
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| 07 | Let the experts support you | Implementation, training and a customer success manager, plus a monitoring and response service for day-to-day operations across thousands of sites. |
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About the authors

Alison Riggott

Director of Clinical Solutions

More than 20 years in clinical trials operations oversight. A qualified pharmacist, Alison held global clinical roles in pharma, CRO and the medicines regulatory industry before joining Controlant.

Adalheidur (Ada) Pálmadóttir

VP Business Development

Leads the global roll-out of Controlant's real-time visibility solutions. Expert in sales, operations, marketing and pharma partnerships; a licensed pharmacist with an MBA.

Carsten Lützhøft

CCO

Extensive experience of process digitalization in global manufacturing and supply chain. Board member and advisory board chairman in aviation and health tech scale-ups.

Vicki Preibisch

VP Sustainability

Heads ESG and a team of sustainability professionals, helping customers deliver on their climate strategies. Chair of the UN Global Compact Leadership Council for Iceland.

Talk to our team

Fast forward to a zero-waste clinical supply chain.

Our experts can show how Controlant's real-time visibility, platform and monitoring and response services can be tailored to your studies, to bring new treatments to patients faster and more sustainably.