WHITE PAPER

Rethinking waste management in clinical supply chains

Unlocking fulfillment, agility and efficiency in an uncertain trial landscape

By Regi T George, Prashant Khare, and Raghuram Mutya

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In clinical supply, waste often reflects the price of certainty. Unpredictable enrollment, complex dosing and regulatory constraints all have a negative impact. To manage these factors, organizations default to high overage and rigid buffers—which often create even more waste.

But waste reduction is not just a cost-saving exercise. It's a strategic lever.

In this white paper, we will explore:

- Why waste reduction is a lever for agility, fulfillment and trial scalability
- Where and why waste occurs across the supply chain
- How organizations define and measure waste—and why a more nuanced definition is essential
- Three proven strategies to reduce waste without compromising fulfillment

By minimizing unnecessary overage, companies can improve fulfillment agility, reduce supply costs and enhance responsiveness to trial changes. In an environment of growing trial complexity and resource constraints, reducing waste is about enabling smarter, faster execution.

Only 40% of manufactured clinical supplies are ultimately administered to patients on average, with the remaining 60% lost across the supply chain.

Balancing waste in clinical trial supply chains with patient fulfillment needs

In clinical trials, where patient safety, protocol adherence and study timelines are non-negotiable, the clinical supply chain is tasked with ensuring 100% patient fulfillment while minimizing waste and total supply cost. Yet the growing complexity and scale of today's clinical trial landscape has made this balance increasingly difficult.

The number of active clinical trials over the past decade has significantly increased, spanning more therapeutic areas, trial phases and geographies. Alongside this expansion, comparator-based trials have become far more common, adding substantial cost, coordination and regulatory complexity to trial execution. These shifts place even greater pressure on the clinical supply chain to operate with precision while managing new layers of uncertainty.

To avoid stockouts, most clinical supply chain teams routinely plan for 150% to 200% overage to account for unpredictable enrollment, attrition and country-level variability. Regulatory labeling requirements, rigid kit configurations and short shelf lives further limit the ability to repurpose inventory across studies or regions. Without real-time visibility into inventory and patient usage, supply plans are often built on static assumptions rather than adaptive intelligence.

FIGURE 1:

Tracing waste across the clinical supply network

Manufacturing facility	Packaging and labeling depot	Country or hub depot (distribution warehouse)	Clinical sites
Upstream demand for drug products and drug substances	**SKU demand plan for packaging and labeling**	**Units expired or unused**	**SKUs received and consumed at sites**
Unpredictable demand Patient enrollment and attrition at sites are unpredictable, so most organizations plan for high overage, leading to excess production of drug product and drug substance.	**Regulatory labelling challenges** Kits must be labeled by country- and trial-specific regulations, making it difficult to repurpose inventory when demand forecasts shift and resulting in high wastage.	**Expiry events** Depots and sites are oversupplied to buffer demand variability, but limited visibility into usage leads to large volumes expiring unused. **Damaged material** Transportation between depots often results in wastage from temperature excursions, extended transit times or shipment mishandling.	**Unused inventory** High overage strategies and inefficient planning drive product expiry and unused stock at sites. **Dosing-level variability** Supplies are planned at the highest possible dose, but actual dosing varies by patient weight, body surface area or lab results, leaving residual or unused kits.

Planning based on more accurate assumptions, forecasting and end-to-end visibility helps enable higher agility across supply chain functions and allows capabilities to maintain 100% fulfillment with lower in-hand inventory.

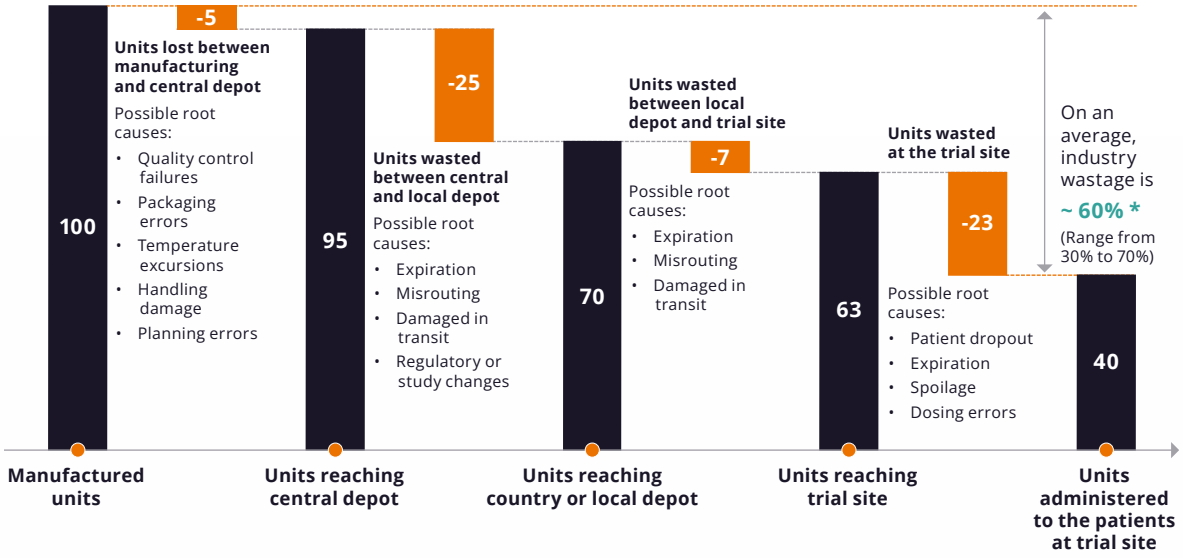
The consequences are systemic: excess production, overshipment, scrappage and expired materials across global depots, distribution warehouses and clinical sites. These are symptoms of a structurally misaligned model, one where overcompensation for risk has become standard practice. The model needs to shift from reactive logistics to intelligent, anticipatory supply orchestration. This means reinforcing the planning foundation with accurate forecasting, dynamic planning parameters and end-to-end visibility from production through patient administration.

Understanding waste across the clinical supply chain

Only 40% of manufactured clinical supplies are ultimately administered to patients on average, with the remaining 60% lost across the supply chain. This waste builds up progressively at each stage, starting from manufacturing and packaging to depot storage, distribution and final site-level handling. While exact loss percentages vary across organizations and studies, the underlying root causes remain consistent (see Figure 2).

FIGURE 2:

Drivers of waste across the clinical supply network



Note: Assumes 100 units were produced at the manufacturing unit to support the study.

* Based on ZS's internal study: An interview of various industry leaders, desk research and industry articles from MCK, IQVIA, etc.

Most clinical supply models have limited ability to adapt to real-world variability because they're build for compliance, not agility. This rigidity amplifies waste, tying up working capital, reducing responsiveness and driving unnecessary operational churn. As organizations scale trials and pursue greater efficiency, waste reduction must be treated as a strategic priority, not a downstream fix. It starts with visibility but demands stronger forecasting, smarter planning and proactive intervention.

Defining waste in clinical supply chain management with consistent measures

Across organizations, waste is framed through varying operational, financial and regulatory lenses. The lack of a common industry definition creates a challenge for understanding what constitutes avoidable loss. Benchmarking becomes difficult and limits systematic reduction efforts across the industry.

Why defining clinical trial waste remains a persistent challenge

In commercial supply chains, waste is typically defined through direct financial measures like write-offs or obsolescence. The same is not true for clinical supply chains, which face greater ambiguity due to fluctuating trial demands, patient-critical constraints and regional regulatory complexity. Even within the same organization, different functions apply distinct lenses:

- Finance may define waste in terms of inventory write-offs or stranded costs at the end of a quarter
- Clinical operations may only flag waste when it disrupts site-level fulfillment or patient access continuity
- Supply chain teams may assess waste as excess inventory—either held or shipped—relative to actual usage

This lack of a unified view results in inconsistent metrics and fragmented decision-making. What one team views as waste, another may consider necessary buffer stock.

While waste has no consistent definition across the clinical supply industry, we have observed a few commonly used interpretations across organizations:

- **Volume-based definition:** Any kit that is manufactured but ultimately not administered to a patient. This includes expired kits, returned or quarantined inventory and excess supplies likely to go unused. This view is most common but varies with what stages of the supply chain are included.
- **Stage-based or end-to-end loss model:** The cumulative product loss across the supply chain—from production to site. This includes waste due to expiry, breakage, mislabeling, temperature excursions and returns. This loss is often tracked by study or geography.
- **Cost-based definition:** The total dollar value of unused investigational product, accounting for drug substance, packaging, labeling, shipping and storage. This lens helps tie waste to budget and ROI decisions.
- **Root cause-based definition:** Inventory written off due to avoidable events such as inaccurate forecasting, overshipment, labeling errors, regulatory delays or last-minute protocol amendments. These events can be used to create learning and process improvements.

- **Study-unattributed waste:** Waste that cannot be traced to a specific protocol, often due to pooled production for multiple studies, canceled studies or early termination. These are typically tracked at a portfolio, therapy area or company level.
- **Shelf life-driven write-downs:** Waste triggered by short or mismatched shelf lives, especially when the product cannot be reused across studies due to labeling or formulation constraints.
- **Time-window expiry (less common):** Inventory that technically hasn't expired but cannot be used within the remaining study timeline or shipment window, rendering it functionally obsolete.

Each definition offers a valuable perspective. But benchmarking and strategic planning are difficult unless organizations align on a common, multidimensional definition (volume + value + attribution). A unified view is foundational to enable targeted reduction and cross-functional accountability.

A holistic perspective: What should be considered waste

While most organizations agree on the need to reduce waste, few align on what should actually count as waste. Definitions vary. Some consider only expired kits. Others include unused stock across the network. Many (but not all) exclude financial valuation. This lack of clarity hinders benchmarking and prioritization.

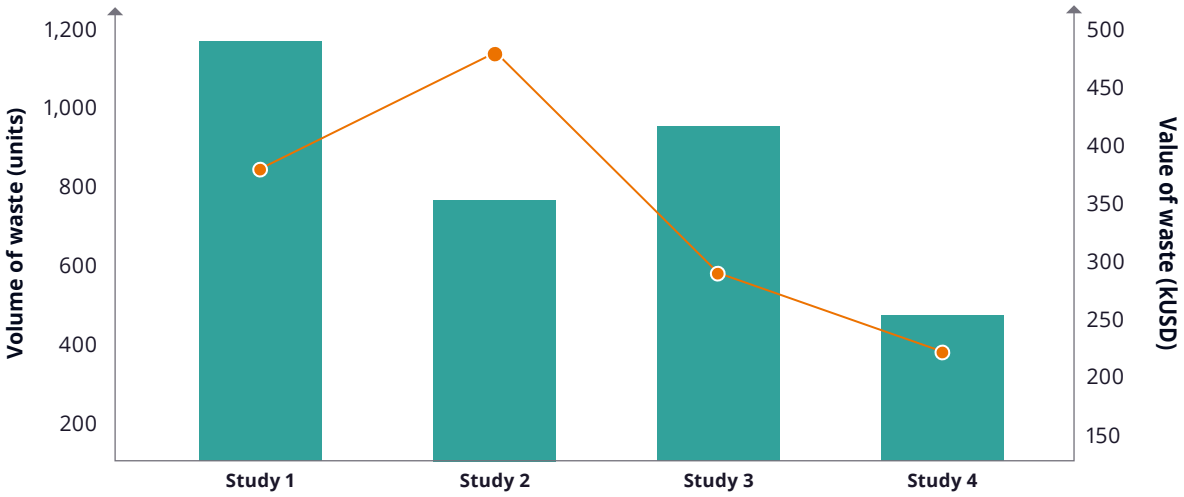
These differences underscore the need for a unified definition. We recommend:

Clinical supply chain waste = **Any investigational product manufactured but not administered to a patient, regardless of location, measured in both volume (units) and value (cost of goods, packaging and distribution).**

This two-dimensional approach captures both clinical impact (how much is lost) and business impact (what it costs), enabling standardized comparisons across studies and informed trade-off decisions (see Figure 3).

FIGURE 3:

Supply waste value and volume by study



By anchoring the definition to patient administration, teams eliminate ambiguity. If a unit never reaches a patient, it's waste.

Align, benchmark, improve: The path to waste optimization

A clear definition is the first step to turning waste into a measurable, improvable outcome. Without a shared definition rooted in both volume and value, forecasting and planning improvements will fall short. Ambiguity breeds fragmentation; clarity enables accountability.

Organizations should begin by aligning on a common definition across supply chain, finance, clinical and quality. Once aligned, the organization should:

- Benchmark current waste levels based on internal goals and risk appetite
- Set realistic improvement targets tied to organizational maturity
- Deploy targeted strategies and track impact over time

This structured approach not only drives internal alignment but also builds the foundation for continuous improvement and long-term efficiency. With this definition and framework in place, we now turn to the actionable strategies that organizations are using to reduce clinical supply waste systematically.

3 proven strategies to reduce waste in clinical supply chains

Reducing waste in the clinical supply chain doesn't hinge on a single solution. Rather, it requires targeted, scalable strategies tailored to trial complexity, operational maturity and risk tolerance. While many levers exist—from drug pooling and portfolio planning to digital labeling and efficient batch release—we've seen these three high-impact strategies consistently drive results across sponsors:

- Intelligent waste tracking to enable early detection and action
- Precision demand planning to align supply with dynamic trial realities
- Trial archetyping to preempt waste through data-driven planning templates

These strategies are not comprehensive but illustrative, drawn from real-world experience of sponsors looking to build more agile, waste-aware clinical supply chains.

Strategy 1: Enabling visibility through intelligent waste tracking

The timely tracking and measuring of inventory and waste is not just an operational discipline. It's a strategic lever for reducing costs and improving agility. When waste is monitored and made visible through integrated reporting and analytics, supply teams can shift from reactive mitigation to proactive intervention—addressing not only waste but the inefficiencies that create it (see Figure 4).

FIGURE 4:

Building visibility for clinical waste tracking

Key activities	Outcomes
Real-time inventory snapshot	
An up-to-the-minute view of inventory across all locations, categorized by status (available, quality, expired, etc.) and product type (FDP, DS, DP), linked to specific studies or programs	» Optimize reordering schedules » Avoid stockouts » Minimize excess inventor and reduce overall costs
Inventory scrap and SLOB reporting	
Detailed reporting of scrap and SLOB, with snapshots and trends across locations by studies	» Perform targeted actions to repurpose SLOB » Reduce risk of obsolescence and associated write-offs
Scrap and SLOB cost reporting	
Quantify the financial impact of scrap and SLOB to highlight areas for cost-saving opportunities	» Correlate scrap costs with specific studies or products » Understand of the financial burden of waste » Identification of high-cost scrap areas
Patient and study impact report	
Historical event report and trends on impact to patient, study, service levels due to high scrap	» Assess impact of waste or inventory issues on patient outcomes or study timelines » Drive a patient-centric approach to inventory management

Effective waste reduction starts with the ability to observe, interpret and act on supply chain signals. Rather than building workflows for every node, teams must assemble a coherent view of where and why waste occurs.

On the stock side, real-time inventory snapshots reduce overordering and redistribution, helping planners and depot leads understand the available stock, location and alignment with short-term demand. Scrap and SLOB (slow-moving and obsolete) reporting prompts timely interventions before expiry by highlighting aging or underused stock.

On the financial side, cost attribution reframes waste as a financial risk, enabling leaders to prioritize better.

And then there's the safety issue. Patient and study impact reporting ties waste to clinical consequences, such as missed doses or protocol deviations, making waste management in the clinical supply chain a patient safety issue, not just a logistics concern.

These capabilities transform inefficiency into a measurable, actionable signal by quantifying and contextualizing waste.

Building real-time visibility with integrated dashboards and alerts

To operationalize this intelligence, organizations must move beyond disconnected reports. Dashboards built from curated, high-fidelity data streams give supply, clinical and quality teams a shared understanding of risks and priorities. Dashboards should be tailored to role-specific needs. Planners need signals related to expiry risk, stock imbalances and shipment timing. Depot and warehouse managers need visibility into dwell times, temperature hold statuses and replenishment rhythms. Clinical teams need to know about trends in site consumption, missed dispensing events and overage and utilization benchmarks.

Key data sources that feed this ecosystem include:

- IRT systems (enrollment, dosing and dispensing behavior)
- ERP/WMS platforms (inventory movement, batch aging)
- CTMS/eTMF (site activation, protocol amendments)
- QMS systems (quality rejections, temperature excursions)
- Logistics platforms (shipment delays and transit conditions)
- External vendor/3PL reports (stock held by packaging vendors, CDMOs, outsourced depots)

When stitched together, these inputs provide a live, end-to-end view of ongoing operations that help supply teams prevent waste before it materializes and act swiftly when supply risks emerge.

Tactical considerations for implementation

Implementing a visibility-driven waste tracking strategy is less about introducing tools and more about designing an interconnected, insight-led way of working. Clinical supply chain leaders should prioritize:

Building a trusted inventory backbone. Fragmented inventory data across systems leads to mismatches in product codes, site IDs and kit references. Organizations can invest in a master data management or data integration solution to reconcile discrepancies. They can also define data governance standards for key entities such as inventory and establish stewardship roles to ensure timely correction and consistent accountability.

Integrating external inventory into the visibility framework. Accessing inventory data from CDMOs and 3PLs through portals delays insights and limits real-time visibility. By building data-sharing pipelines to integrate external stock into their ecosystem, organizations can enable timely, end-to-end decision-making.

Designing dashboards to drive timely actions. Building views can surface anomalies such as threshold breaches, overage buildup and expiry risk. Integrating standard operating procedures or decision intelligence tools can then trigger the appropriate response. This ensures visibility leads to consistent and timely interventions.

Embedding visibility insights into governance routines. Key insights—such as depot overage trends, kit expiry risks and site utilization variance—should be aligned with the specific decisions made in CD&OP (e.g., overage policy adjustments), CD&OE (e.g., midstudy reallocation) and study startup reviews (e.g., site prioritization). To ensure follow-through, organizations should assign action owners for each flagged issue and track closure status in cross-functional forums.

Using waste signals to refine planning logic. Organizations should treat recurring waste patterns, like persistent depot overstock or frequent site expiries, as feedback loops. These waste patterns can then link back to flawed planning inputs (e.g., misaligned activation rates, rigid buffers or inaccurate country splits). These can then be adjusted to demand drivers and overage policies accordingly in future trials.

Strategy 2: Precision demand planning through a forecast-driven clinical supply alignment

Accurately estimating supply needs across geographies, timelines and protocol variants is central to reducing overage, minimizing waste and avoiding stockouts. Precision demand planning offers a structured approach that combines forecast intelligence with dynamic supply modeling to enable clinical supply chains to align trial demand with depot-level inventory strategies.

Traditional buffer-based planning often leads to excessive production and expiry. Precision planning, however, leverages patient-centric inputs to shape inventory decisions proactively, resulting in less redundancy, more responsiveness and improved operational efficiency.

Where planning should be anchored—and why

Precision planning operates at two distinct levels:

- **Enrollment forecasting** is performed at the study, site, country and treatment arm levels, where patient recruitment actually takes place. Forecasting at this level captures real-world site-level variability in activation, screening and recruitment velocity.
- **Product demand planning** is aggregated at the supplying depot level—typically corresponding to the study-country-arm, where inventory is stored and dispatched. Enrollment forecasts and dosing schedules are used to forward-calculate kit requirements, which are then rolled up to drive depot-level supply decisions.

This layered approach ensures planning reflects on-the-ground reality while focusing inventory decisions where stock is physically managed.

Why should one not anchor supply planning at the site level?

Minimal waste occurs at the site. Site-level inventory is lean, driven by IRT-managed resupply aligned with upcoming visit schedules.

Inventory is held upstream. Scrap accumulation and overage typically happen at central and regional depots.

Complexity outweighs value. Modeling for every site-cohort-arm adds unnecessary granularity without yielding better decisions.

Understanding how demand is generated

Product demand in clinical trials is driven by three primary inputs:

- **Planned enrollment:** The number of patients expected to be randomized per site and arm
- **Dosing schedule:** Kit configuration and frequency per patient
- **Attrition rate:** Dropouts, missed visits or early discontinuations that affect actual consumption

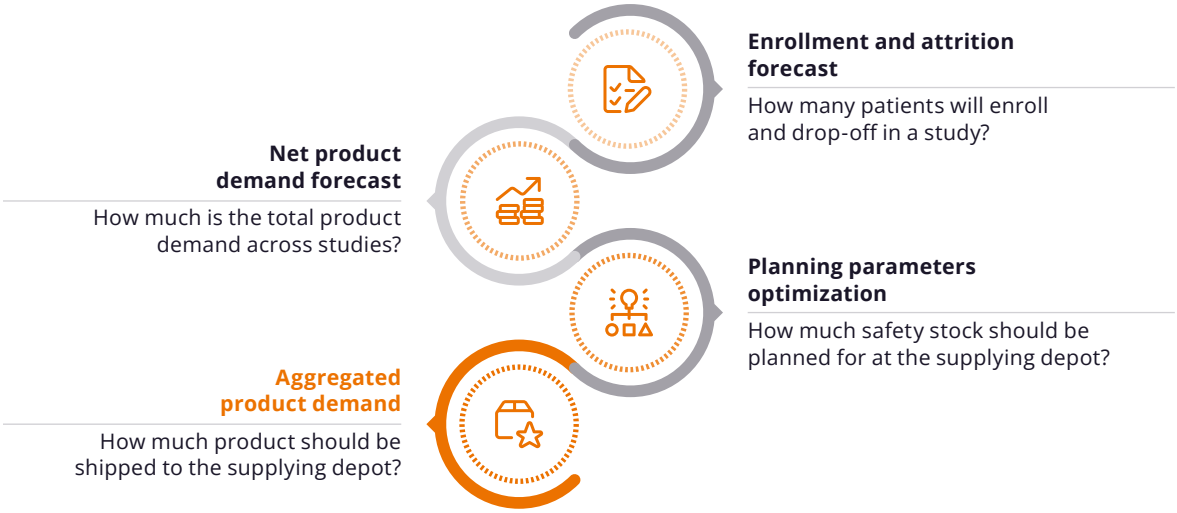
Combined, these inputs form a time-phased projection of required kits per protocol arm. Trial-specific changes such as amendments, geographic variations or staggered activations further reinforce the need for predictive demand forecasting.

Demand planning powered by 3 core models

The outcomes of three core data science models must come together to generate reliable, product-level demand plans.

FIGURE 5:

Framework for clinical demand planning



Enrollment forecasting and attrition: Forecasts patient enrollment using inputs like site readiness, historical activation patterns, country recruitment trends and protocol complexity. This sets the baseline for expected demand.

Net product demand forecast: Adjusts for discontinuation rates and adherence to calculate how many kits are needed throughout the study.

Planning parameters optimization: Uses simulation to account for supply disruptions, lead time variability and demand uncertainty—ensuring fulfillment while minimizing overage.

Aggregated product demand: Consolidates kit requirements from site-level forecasts into a single plan at the supplying depot level, enabling more effective stocking and shipment decisions.

Together, these models form a predictive framework that aligns supply execution with real-time trial dynamics.

Tactical considerations for implementation

Implementing precision demand planning requires both technical rigor and operational governance. Consider the following actions:

Tracking and evaluate planning accuracy. Monitor metrics like forecast errors and actual kit usage to detect volatility. High variance often signals flawed assumptions or changes in enrollment patterns.

Designing for adaptive replanning. Feed actuals from IRT—such as enrollment, attrition and dispensing—into rolling forecasts. This feedback loop improves midstudy responsiveness and minimizes waste.

Limiting the number of planning parameters. Avoid excessive variables. Focus on high-impact drivers like enrollment velocity, dropout rates, lead time, dosing regimens and safety stock.

Integrating forecasts into governance frameworks. Embed forecasts into operational routines (S&OE, risk meetings, startup reviews) to drive timely action and cross-functional ownership.

Applying risk-based planning using simulation. Use Monte Carlo or scenario-based simulations to model a range of potential demand curves. Select planning strategies that match your risk appetite and inventory constraints.

Strategy 3: Trial archetyping for proactive scrap reduction

While clinical trials vary in design, inventory waste drivers often follow repeatable patterns. Most organizations address scrap reactively after kits expire or are written off. A more proactive approach begins earlier: identifying waste risk before it materializes. This is the core of trial archetyping—analyzing historical trials, benchmarking market analogs and using pattern recognition to classify studies by shared waste profiles.

By understanding which types of trials tend to generate high scrap—and why they do it—supply teams can embed this intelligence into study planning, protocol design, overage policies and depot stocking strategies.

How archetyping enables predictive waste planning

Trial archetyping groups studies into defined categories—or archetypes—based on similarities in design, behavior and waste risk. It combines historical analysis, external benchmarking and diagnostic insights to guide planning. Key steps include:

- Benchmarking past trials and analogs to flag high-waste studies
- Attributing waste to root causes like protocol amendments, delayed activations or overshipment
- Identifying repeatable trends across trial features (e.g., phase, indication, country spread and dosing complexity)
- Segmenting trials into archetypes that reflect typical risk profiles and planning requirements

Each archetype becomes a planning asset, providing foresight into likely waste scenarios and informing tailored supply strategies.

Key focus areas for archetyping analysis

Effective archetyping depends on analyzing trials from multiple angles. Three areas in particular provide the strongest insight into where waste originates and how it can be prevented.

Scrap root cause analysis. The first step is to move beyond simply identifying where waste occurs and focus on understanding why. Trials are analyzed for waste stemming from:

- Protocol changes or late design shifts
- Site inactivity or underperformance
- Shipment delays or in-transit expiry
- Misaligned overage policies

This diagnostic lens creates a causal map between supply decisions and actual inventory outcomes.

Cross-trial pattern recognition. By aggregating scrap trends across multiple studies, organizations can identify archetypal risk patterns, such as:

- Early-phase trials in rare diseases with frequent protocol modifications
- Multicountry studies with long lead times and low site utilization
- Oncology phase 3 trials with complex dosing and high dropout rates

These patterns become critical for forecasting where waste is likely to materialize in future studies with similar attributes.

Design feature correlation. Advanced archetyping includes quantitative analysis of how specific study design features correlate with waste. For example:

- The number of treatment arms and their dosing variability
- Trial duration and expected treatment adherence
- The geographic footprint and regulatory labeling constraints

Understanding these correlations allows supply and clinical teams to align on risk-informed planning models.

Strategic value of trial archetyping in clinical supply chains

Archetyping moves clinical supply planning away from one-size-fits-all assumptions toward targeted planning templates that reflect historical evidence. There are myriad benefits to this. Forecasting is more realistic when it's based on past patterns. Prebuilt archetype models allow for faster planning cycles. Organizations gain cross-functional alignment on likely waste drivers and stronger upstream influence on trial design and feasibility. Ultimately, archetyping embeds organizational memory into proactive supply planning, turning past lessons into future advantage.

Tactical considerations for trial archetyping implementation

Implementing trial archetyping requires a thoughtful mix of analytics, historical insights and cross-functional alignment. Organizations can take the following actions to help ensure that archetyping delivers actionable planning value:

- **Prioritize root-cause visibility.** Invest in analytics that trace scrap to specific planning missteps (e.g., amendments, delays, forecasting errors).
- **Leverage internal and external benchmarks.** Compare internal trial data with industry analogs to differentiate systemic issues from anomalies.
- **Focus on repeatable patterns.** Target trials with similar design features, such as the number of arms, dosing complexity or country mix, to identify recurring waste profiles.

- **Balance complexity with usability.** Avoid overcomplication. Limit archetypes to dimensions that meaningfully influence planning outcomes and scrap risk.
- **Embed archetypes into planning processes.** Drive real adoption by embedding archetypes into feasibility reviews, overage policy setting and depot planning.

Clinical supply waste: The time to act is now

The cost of inaction will only continue to mount. Waste drains millions through expired inventory, stalled recruitment and fragmented planning. As trials grow more complex and resources more constrained, reducing waste is central to protecting speed, certainty and patient access. Waste reduction is not just about efficiency. It determines how quickly patients gain access to therapies and how reliably they receive them. Choosing to act means choosing to deliver with certainty.

About the authors

Regi T George has over 15 years of experience in life sciences, specializing in data-driven analytics across commercial and supply chain domains. He now leads the clinical supply chain practice at ZS, where he partners with pharmaceutical and biotech organizations to shape strategy, enhance agility, and drive large-scale transformation with greater efficiency. His work focuses on advancing the adoption of AI, machine learning and digital innovation to reimagine supply chain models, create new sources of value and establish thought leadership that helps clinical supply chain teams achieve faster speed, improved outcomes and sustainable impact.

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