RTSM Drug Supply & Resupply Guide

Understanding supply strategies, expiration buffers, inventory monitoring, and automated resupply.

Your study keeps clinical sites stocked with drug supply through Veeva RTSM. This guide explains how that happens: the ways shipments can be triggered, how supply levels and expiration safeguards are configured, how to monitor on-site inventory, and how the system calculates when and how much to ship. Use it as a reference whenever you're setting up a study, adjusting supply settings, or troubleshooting a shipment question.

1. Resupply Methods

RTSM supports three ways to keep a site stocked, so you can match the approach to your study's design, depot setup, and enrollment pattern.

Method	How it works
Manual Shipments	An authorized supply team member (e.g., an unblinded Inventory User) requests shipments on demand. Nothing happens automatically.
Automatic Static Shipments	The system checks inventory every night and automatically ships more stock whenever a site's inventory falls to or below its Alert Level, bringing it back up to its Baseline Supply.
Automatic Predictive Shipments	The system checks every night and automatically ships stock based on forecasted demand from subjects' upcoming scheduled visits, plus a safety buffer.

2. Supply Strategies & Configuration

Strategy types

Every depot and site is set up under one of three strategy types:

- **Origin-Level:** warehouses/depots where RTSM starts tracking inventory, and any site supplied manually. If a site is switched to manual requests only, it automatically becomes Origin-Level and uses only its Alert Level to flag low stock.
- **Depot-Level:** depots that both receive system-managed shipments and send system-generated shipments on to sites.
- **Site-Level:** clinical sites that receive shipments from a supplying depot.

Customizing and tiering strategies

- **Enrollment-based tiering:** your team can build and name strategies suited to groups of sites — commonly by enrollment volume (e.g., High, Baseline, or Low Enrollment) — to avoid overstocking or running short.
- **Build vs. live flexibility:** initial strategies are set up during study build and documented in the User Requirements Specification (URS). Once the study is live, authorized users can still adjust parameters or create new strategies directly in production.

Where strategy values can be set

- **Country level:** values set for a country automatically apply to every current and future site in that country assigned to the strategy.
- **CTM (Clinical Trial Material) Type level:** used only for static resupply settings; can be set study-wide, by country, or by site.

- **Single site vs. multi-site sharing:** a strategy built only with site-specific values can only be used by that one site. To share a strategy across sites, build it with general, country-level, or enrollment-tier values instead, and assign it wherever it's needed.

Visibility and permissions

- **Site Rollup Report:** shows the live resupply values driving each site, based on its assigned strategy. Update the strategy, and every linked site reflects the change immediately.
- **User access:** by default, the Inventory User (IU), Clinical Project Manager (CPM), and Clinical Supplies/Project Operations (CPO) roles have view-only access to the Resupply page. On request, the IU role can be granted permission to add or edit resupply values and strategies.

3. Core Resupply Parameters

These are the settings that determine when a shipment is triggered and how much is ordered.

Resupply type	Parameter	What it does
Static	Initial Supply	The quantity of each CTM type sent in a site's first shipment, triggered at site activation or a defined first-subject milestone.
Static	Alert Level	The minimum number of units to keep on hand. When inventory falls to or below this, the nightly job triggers a resupply. (Also feeds the Trigger Inventory calculation in Predictive resupply.)
Static	Baseline Supply	The target maximum stock level. When a shipment is triggered, enough units are ordered to bring inventory back up to this amount. (Also feeds the Target Inventory calculation in Predictive resupply.)
Static	Min Days Between Shipments	A minimum number of days that must pass since the last shipment before another can be generated, regardless of inventory level. Set to 0 to disable. Note: using this setting raises the risk of an on-site stockout if enrollment speeds up.
Predictive	Lead Days	The estimated transit time, in days, from when a shipment is generated to when it arrives on site.
Predictive	Trigger Days	The minimum number of days of upcoming visit demand that on-site inventory must cover before a shipment is triggered.
Predictive	Target Days	The number of days of upcoming visit demand the system aims to cover when it generates a shipment.

4. Expiration Buffers & Offsets (DNX Settings)

Four settings protect against kits arriving or being dispensed without enough shelf life left. All four can be configured by CTM Type, Site, or Country.

Setting	Short name	How it protects supply
Do Not Ship Buffer	DNSb	The number of days before expiration at which a kit stops being eligible for static-resupply shipments.
Do Not Include Buffer	DNI	The number of days before expiration at which a kit is excluded from usable inventory in both static and predictive calculations.
Do Not Ship Offset	DNSo	Used in predictive resupply to confirm a depot kit has enough shelf life for an upcoming visit: the kit must expire after the visit's assumed ship date plus this offset. If that requirement falls earlier than the DNI cutoff, the system falls back to the DNSb instead.
Do Not Dispense Offset	DND	The number of days before expiration at which a kit stops being assignable to a subject, so it won't expire before that subject's next visit.

Example — Do Not Ship Offset

A subject's visit is scheduled for January 1 and the DNSo is 17 days. The kit must expire after January 18 to ship. If the DNI cutoff falls earlier than January 18, the system uses the visit date plus the Do Not Ship Buffer instead.

5. Managing Supply During the Study

As enrollment changes or the study nears close-out, your team can adjust resupply behavior at the strategy, site, or method level.

Reducing shipment frequency

- Lower Target Days and Trigger Days so the system forecasts fewer days ahead.
- Lower the Alert Level so static shipments trigger less often.
- Set a Minimum Days Between Shipments to space shipments out.
- Near close-out, switch sites to Manual Shipments so the unblinded Inventory User manages final orders directly.

Supply risk to keep in mind

Setting Trigger Days, Lead Days, or Alert Levels too low — or enforcing a Minimum Days Between Shipments — increases the risk of running short on active subjects' supply.

Temporary site-level overrides

If one site needs a short-term increase or decrease in shipments, add site-specific resupply values directly on the Resupply page and enable them. Once disabled, the site automatically reverts to its underlying strategy.

Updating a site's strategy or resupply type

- **Reassigning strategies:** change a site's assigned strategy (e.g., from High to Low Enrollment) directly on the Site Information form.
- **Switching Static ↔ Predictive:** also done from the Site Information form, once predictive settings are configured for the site's strategy.

6. Monitoring On-Site Inventory & Kit Statuses

Expiration color indicators

- **Orange:** the kit has entered its Do Not Include (DNI) window. It's still Available and counts in total Available Inventory, but it's tracked in the Expiring column and excluded from usable (Virtual) Site Inventory.
- **Red:** the kit has passed its expiration date and is waiting for the next nightly job to move it to Expired status.

Quarantined kits

> **Best practice**
> Quarantined kits still count toward Available Inventory. Because that inflates Virtual Site Inventory, unresolved quarantined kits can prevent a needed resupply shipment from triggering — risking a shortage. Update quarantined kits to Available or Unusable promptly to keep resupply calculations accurate.

7. How Resupply Is Calculated

The calculations below run during the nightly job to decide whether a site needs a shipment, and how much.

Key variables

Variable	Definition & formula
Actual Site Inventory	All physical kits at the site currently in Available or Quarantined status.
Virtual Site Inventory (VSI)	Usable on-site stock plus incoming shipments not yet acknowledged: Available Inventory + On Order − Expiring (kits within the DNI window).
Last Shipment Date	The request date of the most recent shipment in Requested, Sent, or Received status. Cancelled, Missing, and Damaged shipments don't count.
Trigger Inventory (TRI) — Predictive only	Alert Level + forecasted demand over (Trigger Days + Lead Days). A shipment is requested when VSI falls to or below this.
Target Inventory (TAI) — Predictive only	Baseline Supply + forecasted demand over (Target Days + Lead Days). When a shipment triggers, enough is ordered to bring VSI up to this level.
Predict Only If Next (event setting)	When set to True, that visit only counts in the forecast if it's the subject's immediate next scheduled visit. **(To update this setting customer must submit a CCR)**

Static resupply calculation

Each night, the system compares Virtual Site Inventory (VSI) to the Alert Level, using that day's DNI and Do Not Ship dates. If VSI is at or below the Alert Level, it orders enough to bring inventory back up to the Baseline Supply.

Predictive resupply calculation

Predictive resupply forecasts demand using two assumptions:

- **Predictive Availability Assumption:** which subjects are included in the forecast — by default, the start of the visit window (earliest expected visit date).

- **Predictive Shipping Assumption:** the expected date of drug usage shown in the forecast — by default, the end of the visit window (latest expected dispensing date).

When VSI drops to or below the Trigger Inventory, a shipment is generated to bring stock up to the Target Inventory (order quantity = Target Inventory − VSI):

	Kit Type A	Kit Type B
Target Inventory	12	10 (2 + 8)
Virtual Site Inventory	2	1
Forecast shipment	12 − 2 = 10 kits	10 − 1 = 9 kits

The blue DNS date

In predictive calculations, the Do Not Ship (DNS) date is normally the visit's event date plus the Do Not Ship Offset. If that date falls earlier than the DNI date, the system automatically falls back to using the Do Not Ship Buffer instead and shows the DNS date in blue — this stops the system from shipping a kit that would land in its DNI window on arrival and immediately trigger a replacement.

8. Additional Resupply Settings (These settings can only be changed by Veeva and would require either a CCR or SCR)

Setting	Definition & function
KitTypesToTrigger	The number of distinct kit types that must reach their Alert Level at a site before a shipment is generated.
ResupplyNoSingleTreatKit	Works with Primary/Secondary weighting in the CTM Types table to add an extra kit when a shipment would otherwise contain only one treatment kit. Disabling it turns off that weighting and extra-kit logic.
Include in Predict (Kit Type)	When set to True for a kit type, that kit type is included in predictive inventory calculations.

Glossary of Abbreviations

Term	Stands for		
CTM	Clinical Trial Material	DND	Do Not Dispense Offset
DNX	Umbrella term for the four-expiration buffer/offset settings below	VSI	Virtual Site Inventory
DNSb	Do Not Ship Buffer	TRI	Trigger Inventory
DNI	Do Not Include Buffer	TAI	Target Inventory
DNSo	Do Not Ship Offset	IU / CPM / CPO	Inventory User / Clinical Project Manager / Clinical Supplies or Project Operations