

Veeva RTSM Resupply: The Fundamentals and Beyond

Clinical trials with a large number of sites and dispensation visits have a higher need for thoughtful resupply planning and automatic shipments. There is arguably correlation between the number of sites, countries, depots, subjects, and visits and the importance of an effective trial supply management solution.

An RTSM (randomization and trial supply management) system is not only purpose-built to meet the randomization requirements of a clinical trial but also the trial supply management needs. It should offer a robust, regulatory-compliant option for generating and tracking shipments from depot to depot, depot to site, site back to depot (returns), and even site-to-site transfers when required.

There are fundamental resupply capabilities that any successful RTSM solution should deliver:

1. 'Static' initial and resupply settings
2. Predictive resupply
3. Automated and manual requests
4. Low stock alerting

Veeva RTSM supports these fundamentals in the following ways:



'Static' initial and resupply settings

Sometimes referred to as 'trigger resupply' or 'buffer,' these static numbers control what supply to send to sites initially (at activation, screening, or first randomization, depending on design) and when to trigger additional supply.

Resupply Levels							
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Site Settings							
Supply Defaults							
Country		ALL					
For Site		ALL					
Export							Rows: 20
	Country	Site	Type Name	Initial Supply	Baseline Supply	Alert Level	
	United States	001	Active 5 mg	12	8	4	
	United States	001	Placebo 5 mg	12	8	4	
	United States	101	Active 5 mg	12	8	4	
	United States	101	Placebo 5 mg	12	8	4	
	Germany	102	Active 5 mg	10	6	2	
	Germany	102	Placebo 5 mg	10	6	2	

In this example, for Site 102, 10 of each kit type will be sent initially. Subsequently, when the amount of either active or placebo reaches two, both kit types will be replenished up to six.

Permitted users have the flexibility to amend these settings on demand as we understand recruitment plans may fluctuate.

It is typically recommended to maintain a level of buffer stock. This is to ensure that in the event of any damaged/missing kits and any unscheduled resupply visits, the subject can be resupplied and remain IP compliant. However, if recruitment has ended or supply is limited, this can be reduced or even set to 0 and a predictive-only approach can be taken.



Predictive resupply

Predictive resupply in Veeva RTSM will take into account the ongoing patients at a site as well as pre-determined site settings.

For example, 'lead days' will determine how long the shipment will take to reach the site. Trigger and target inventory days, sometimes referred to as short and long-range windows in the industry, determine the time period to forecast.

Site Resupply Settings							
		Resupply Levels		Site Settings		Supply Defaults	
Country <input type="text" value="ALL"/>							
Export							Rows: 9
Menu	Country	Site	Name	Lead Days	Trigger Inv Days	Target Inv Days	Min Days Between Shipments
...	United States	001	Morganton Internal Medicine	5	14	21	0
...	United States	101	MacDill Clinical Research Center	7	14	21	0
...	Germany	102	UO Research Center	5	14	21	0

These site-level settings, combined with the upcoming patient visits and the dispensation required at these visits, will determine how much additional supply to send to the site in addition to the static settings. This ensures that the supply needs of both new and existing patients are always met.



Automated and manual requests

The Veeva RTSM resupply algorithm runs daily or on demand and takes into account all site settings to automatically generate required shipments.

Manual shipments can be raised ad-hoc by permitted users. For example, if a site has a sudden spike in recruitment, it may be preferred to send a one-off additional shipment manually rather than temporarily amend the site settings and back again.

Sites and depots can be set as static only, predictive, or manual on-demand throughout the study.



Low stock alerting

Veeva RTSM generates low-stock alerts based on study-specific thresholds. This can provide early warning that shipments are outstanding, that depot-to-depot shipments need to be initiated, or that a new manufacturing run may need to be considered for a trial.

Early detection can prevent patient-waiting situations on site or even study stock outages.

Going beyond the fundamentals

The above are examples of functionality that we believe all RTSM systems should provide.

However, there are features within Veeva RTSM that expand upon these and can provide significant value to sponsors and supply management teams.



Partial dose prediction

In trials using titration, there can be many unknowns about whether patients will down-titrate, maintain, or up-titrate from visit to visit.

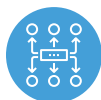
For example, at Visit 2 a subject on 10mg active may move to 5mg, maintain at 10mg or up titrate to 15mg. There is a likelihood they will maintain, but there is a 10% chance of down titration and a 10% chance of up titration.

Veeva RTSM can support partial dose prediction, where the probability of different titrations can be taken into account in order to avoid overstocking for all scenarios as part of the predictive resupply. This can maximize trial supply without putting subject visits at risk.



Resupply calculation visibility

Veeva RTSM provides a unique view into what calculation the system has applied to a site or a shipment. This visibility allows teams to easily understand why the system has or has not raised a particular request without manual efforts and help desk inquiries.



Pre-allocation to subjects

Kits can be pre-allocated to subjects – within a shipment the kits can be associated with the subject ID to ensure they can only be allocated to that specific subject. For example, this can be particularly effective for cell/gene therapy study designs.

The ability to customize Veeva RTSM as well as configure allows any nuances with kit allocation to be supported without the need for manual workarounds.



Site-specific resupply settings

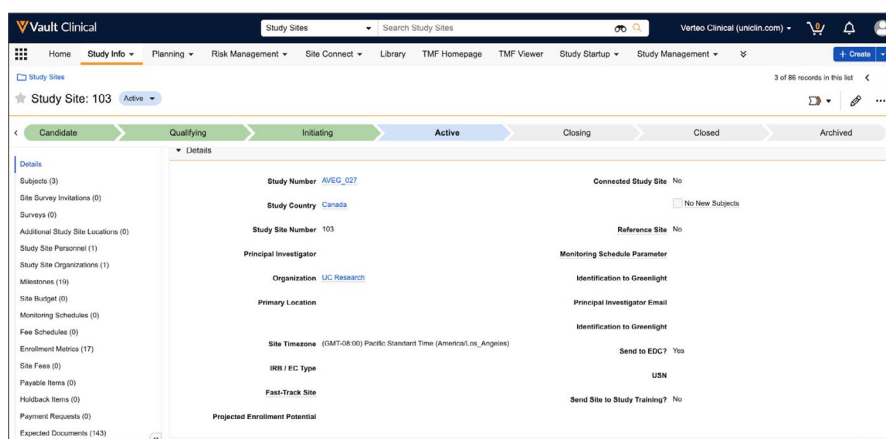
As part of static resupply, Veeva RTSM can support a set of resupply plans and defaults, for example high, medium, low, and very low plans based on expected recruitment. These can then be applied to appropriate sites.

However, we also support the use of site-specific settings and a combination of plans and site settings. There is full flexibility for this to be as broad or as granular as required with minimum configuration effort to tweak throughout the trial lifecycle.



Green light process integration

Connectivity between Veeva RTSM and Vault Clinical applications allows sponsors to utilize the green light information in Vault CTMS/SSU to control site creation activation for shipping in Veeva RTSM. This prevents the effort of duplicating site data entry and helps enforce regulatory compliance.



Service expertise

Resupply settings are of critical importance to the success of a study. Incorrect configuration could under or overstock a site. Overstocking can cause expensive wastage and site inconvenience, but understocking can cause subjects to be lost from the study.

The priorities and needs of an individual trial design can be achieved through thoughtful implementation and flexibility throughout study execution. Veeva RTSM provides an expert services team throughout the entire study lifecycle to guide teams on all resupply options, best practices, and amendments.

We are happy to discuss both resupply fundamentals and beyond for any upcoming trial needs and can demonstrate these different functionalities on request. This is not an exhaustive list of all trial management capabilities, and we are happy to discuss further. Please contact info@rtsm.veeva.com with your questions.