

Veeva RTSM

Veeva RTSM is a fast, intuitive, and complete randomization and trial supply management solution designed to simplify complex processes and expedite clinical trials. It is modular and highly configurable allowing the expert Veeva services teams to design and deliver studies with speed and accuracy.

The extensive feature set allows Veeva RTSM to scale and support a spectrum of different trial design needs and complexities across all therapeutic areas. Connections with the Veeva Vault Development Cloud platform and integrations with third party solutions allow customers to seamlessly utilize Veeva RTSM in their clinical trial technology eco-system.

RTSM Validation System v4

Subjects Activities Shipments **Kits** Admin Profile

Kits Kit List Status history

Show Site 101
Filter By Updated Since ALL

Menu	Site	Kit	Shipment	Subject ID	Activity	Status	Status Date	Requested On	Shipped On	Temp Dev On	Available On	Assigned On
...	101	10043	5002	101-002	Week 4	Assigned	23 Aug 2022	09 Jul 2022	11 Jul 2022		13 Jul 2022	23 Aug 2022
...	101	10390	5005			Available	21 Sep 2022	17 Sep 2022	19 Sep 2022		21 Sep 2022	

Rows: 31

Kit Tracking

RTSM Validation System v4

Subjects Activities Shipments Kits Admin Profile

Subjects Subject List Rollup Report

Show Rand Id Cohort Stratification Next activity
Site 101
Filter By Recorded Since ALL

+ New Subject Export

Menu	Country	Site	Subject ID	Birth Date	Age at Screening	Gender	Previous Treatment	Severity	Status	Status Date	Next Activity	Target Date
...	United States	101	101-001	22 Sep 2007	14	Male	Yes	Mild	Completed	05 Oct 2022	n/a	n/a
...	United States	101	101-002	11 Mar 1949	73	Male	Yes	Moderate	Week 8	20 Sep 2022	Week 10	04 Oct 2022
...	United States	101	101-003	21 May 2004	18	Female	No	Moderate	Week 4	21 Sep 2022	Week 8	19 Oct 2022
...	United States	101	101-004	24 Aug 1943	79	Male	Yes	Moderate	Week 2	27 Sep 2022	Week 4	11 Oct 2022
...	United States	101	101-005	11 Dec 2008	13	Female	No	Mild	Randomized	24 Sep 2022	Week 2	08 Oct 2022
...	United States	101	101-006	13 Aug 1955	67	Male	No	Severe	Randomized	01 Oct 2022	Week 2	15 Oct 2022
...	United States	101	101-007	18 Jul 1971	51	Female			Screened	01 Oct 2022	Randomization	n/a
...	United States	101	101-008	10 May 2007	15	Male			Screened	04 Oct 2022	Randomization	n/a

Rows: 8

Subject Tracking

Benefits

- **Everything you need and only what you need:** modular solution allows you to only use and pay for the functionality you need when you need it.
- **No compromises:** flexible configuration options combined with appropriate customizations achieves the design you want, not what your system provider limits you to.
- **Maximize supply & minimize costs:** adaptable trial supply management settings and expiry management to minimize drug wastage and control the schedule of site shipments.
- **Exceptional service delivery:** proactive project management, communication, and guidance from Veeva RTSM experts at every stage of your trial.

Randomization

Veeva RTSM ensures this critical transaction is completed with timeliness and precision.

- Multiple randomization schemas are available including static, stratified (single or multi-variable), dynamic/minimization, forced, and adaptive. Re-randomization is also supported.
- Easily configure eligibility, stratification, and other related questions to randomize subjects appropriately.
- Supports capping and can tightly control sentinel dosing.

Trial Supply Management

Define the optimal clinical trial supply management strategy for your trial's needs.

- A range of methodologies to trigger site shipments including trigger/resupply thresholds, predictive inventory control and just in time options.
- Flexibility to adapt supply settings during study execution (e.g., change resupply levels based on actual site enrollment numbers).
- Track all types of clinical trial supply materials with blinded and unblinded views, temperature management options and connections with shipping providers.
- Supports complex patient dosing schedules including titration and dose probability.
- End to end drug accountability module tracing the full kit lifecycle.

A PROVEN TRACK RECORD

8,500+
sites

45,000+
system users

60+
countries

Additional Features

Tracking Subject Activities

Easily track subject activities including scheduled activities such as screening and enrolling subjects; randomization, drug assignments including titration management, completion, and follow-up; unscheduled activities such as screen failure, early terminate/withdrawal, unscheduled resupply; skipped visits; and emergency unblinding.

Functionality for all trial types

Supports a variety of study designs including crossover studies, sequencing studies, extension studies, multi-cohort designs and sub-study tracking.

Rapid Setup Processes

Modular and highly configurable software enabling customers to achieve faster study set up timelines (as little as 3 to 4 weeks). The architecture also allows customizations to be engineered and deployed if required.

Easy Mid-study Updates

End users with appropriate permissions can easily reconfigure key settings during the course of a study – e.g., “turn on” a cohort, and modify allowable limits on total number of screened and randomized subjects. Amendments requiring a system design change can be implemented rapidly by the Veeva RTSM services team often in days rather than weeks.

Accessible Reporting

Intuitive filterable interfaces allow users to target what information they need to report on when they need it; review details on screen or export on demand to Excel and SAS.

User-friendly Interface

Simple easy to use interface with role and permission-based access. Purposely designed to minimise the number of clicks to complete common tasks and improve the accuracy of site data entry.

Connectivity

Veeva RTSM can function seamlessly with different electronic data capture systems, reporting tools and shipping providers.

Service Expertise

Veeva RTSM is delivered by a services team focused on customer success. The team has a deep understanding of RTSM best practices, system configuration and validation. During set up they work closely with customers to implement with speed and accuracy. Throughout trial execution the project manager and 24/7/365 help desk provide ongoing expertise and support.