

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.

Kit Tracking

| 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 | |

Subject Tracking

| 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 |

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. 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 minimize 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.