

Veeva RTSM

Veeva RTSM is an enterprise standard randomization and trial supply management solution designed to accelerate study timelines and drive operational efficiencies. Guided by experts, Veeva RTSM is delivered by a dedicated services team with deep RTSM expertise, ensuring rapid implementation with precision.

Through flexible configuration options and appropriate customizations, Veeva RTSM tailors each study to meet protocol-specific requirements regardless of trial complexity. Seamless connections with the Veeva Clinical Platform and third-party integrations enable effortless adoption within existing clinical ecosystems.

The screenshot displays the Veeva RTSM Validation System v4 interface. The top navigation bar includes 'Subjects', 'Activities', 'Shipments', 'Kits', 'Admin', and 'Profile'. The 'Kits' module is active, showing a 'Kit List' and 'Status history' tab. Below the tabs, there are filters for 'Show Site' (101) and 'Filter By' (Updated Since, ALL). A table lists kit details with columns: Menu, Site, Kit, Shipment, Subject ID, Activity, Status, Status Date, Requested On, Shipped On, Temp Dev On, Available On, and Assigned On. The table shows 31 rows of data.

The 'Subjects' module is also visible, showing a 'Subject List' and 'Rollup Report' tab. Below the tabs, there are filters for 'Show' (Rand Id, Cohort, Stratification, Next activity) and 'Filter By' (Recorded Since, ALL). A table lists subject details with columns: Menu, Country, Site, Subject ID, Birth Date, Age at Screening, Gender, Previous Treatment, Severity, Status, Status Date, Next Activity, and Target Date. The table shows 8 rows of data.

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	
...	101	10578	5002	101-001								
...	101	10667	5002	101-002								
...	101	11064	5002	101-004								
...	101	11399	5002	101-001								
...	101	11427	5005									
...	101	11700	5005	101-004								
...	101	12222	5005									
...	101	13043	5002	101-002								
...	101	13095	5005									
...	101	13125	5002	101-001								

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.

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.

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.

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.