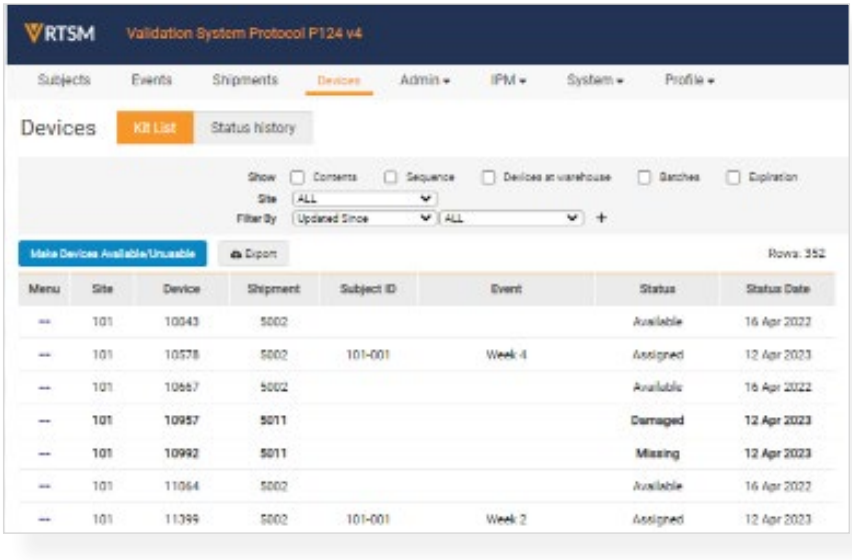
Veeva RTSM

A regulatory-compliant solution for managing medical device supply

Veeva RTSM provides a full range of randomization and trial supply management capabilities to meet the needs of all different trial designs and complexities. It is purpose built for these critical tasks.

Not every trial requires every available feature. Therefore, the system is modular and flexible to meet these varying needs.

A key module supporting medical device trials is **device supply and accountability**.



Demonstrating complete end-to-end traceability for all devices in a clinical trial is of utmost importance, as outlined in section 6.9 of ISO 14155:2011, Clinical investigation of medical devices for human subjects — Good Clinical Practice. The investigator is responsible for documenting the lifecycle of all investigational medical devices at the site, including receipt, use, return, and disposal. Failure to provide sufficient documentation risks an FDA finding and the additional time, cost, and resources to address it.

Veeva RTSM's comprehensive device supply and accountability module can reduce site burden, support regulatory compliance, and provide sponsor oversight. The intuitive role-based user interface allows subject and device management throughout the lifecycle of the trial. The system configurability allows sponsors to easily define any specific naming conventions or preferred workflows to optimize this module for the specific device type and trial design.

Key features of this module include:

- Status tracking history of all uniquely numbered devices including shipment, receipt, allocation/usage, return, destruction
- Automated and/or manual shipments of devices to sites
- Centralized accountability log; easy to view, filter, and export on-demand logs for all applicable device information including batch/serial numbers
- Fully compliant audit trail across all subject and device activity
- Simple, consistent connectivity with Vault EDC, Vault Clinical solutions or integrations to 3rd party systems to eliminate duplicate data entry
- Management and workflow for device issues, e.g., misallocations or missing/damaged devices

In addition to device accountability, sponsors can also benefit from Veeva RTSM's flexible randomization options including simple, blocked, stratified, dynamic (minimization), and re-randomization for trials with randomization needs. Our in-house biostatistics team can generate an appropriate randomization list on behalf of the sponsor or can upload any list(s) provided.

To discuss your randomization and device management needs further and explore the value Veeva RTSM can bring to your next clinical trial, please contact us at info@rtsm.veeva.com.