Veeva RTSM: Integration Best Practices When Integrating with EDC Solutions

EDC (electronic data capture) and RTSM (randomization and trial supply management) are two distinct systems with specific functions, and Veeva believes they should remain as such. Efforts to merge the two creates inefficiencies and compromises. The strategy to keep these solutions stand-alone and connected is explored further here.

Sponsors commonly ask if patient transactions and/or data captured in any EDC solution can be integrated into Veeva RTSM. Many RTSM vendors are eager to please and promote that anything is possible, that all bi-directional integrations can be easily achieved and any data flow can be accommodated however complex.

This article explores why Veeva believes this creates additional risk and is therefore the wrong approach.

Veeva RTSM provides flexible architecture to technically support any integration needs. However, agreeing to a convoluted bi-directional design is not the right thing to do for customer success. It complicates the site experience and creates unnecessary potential points of failure. This can quickly escalate into urgent patient waiting scenarios, patient dropouts, protocol deviations, non-compliance, etc.

Integrations can be kept simple by applying the following guiding principles:

Data required for time sensitive transactions – where the output is needed immediately such as a randomization or kit allocation – should always be entered directly into Veeva RTSM.

Do not enter unnecessary data into RTSM; if it is not required to support accurate randomization and supply management, it does not belong in RTSM.

Do not integrate data from RTSM into EDC if it does not add value to the site data entry workflow.

The following scenarios illustrate the application of these principles.

Screening

Patient screening can be considered a time sensitive transaction. It creates the patient number required for downstream processes, and it is typically required before randomization can proceed.

Numerous EDC forms are associated with a patient screening event to capture demographics, vitals, protocol specific procedures, eligibility, etc. Sites are encouraged to enter EDC data in a timely manner, but in reality these forms are often completed after the event.

In a study design where screening is entered into EDC and integrated into the RTSM solution, any delayed data entry will pose a problem. A patient may be on site awaiting randomization. Without the screening completed in EDC, this cannot proceed as the patient does not exist yet in RTSM. There will be a scramble to enter data into EDC and trigger the integration. A screening CRF contains extensive data points relating to the subject and it may not be clear which specific data points are required as a minimum for the RTSM screening event to proceed. What if the integration is not immediate? Any integration delay or failure will mean timely randomization cannot proceed, and this can snowball into an urgent escalation that impacts the site, sponsor and patient experiences.

Entering screening directly into Veeva RTSM means it can quickly be added if missing at the randomization event (and backdated appropriately), minimal information should be required, and randomization can subsequently be entered with speed and ease. The same is true for rescreening.

Veeva RTSM's robust integration capabilities can instantly create the subject casebook in EDC, and data relevant to the screening CRFs will populate in real time to avoid duplicate data entry and reconciliation effort.

Commonly integrated fields from Veeva RTSM into EDC at screening are:

- Screening/Rescreening Event Date
- Subject ID
- Age / Birthdate / Year of Birth
- Sex
- Informed Consent Date

As a best practice, these should be set to read-only fields in EDC to prevent sites updating in one system and not the other. When Veeva RTSM is used in conjunction with Veeva EDC, the field status can be controlled through the integration. Additionally, a guided navigation experience across the systems and single sign-on with VeevaID provides a more seamless end user experience and connectivity with Veeva CTMS provides real-time visibility into all enrollment data.

Randomization

Randomization is a core function of Veeva RTSM. Like screening, it is a time sensitive transaction. Critical information is determined by RTSM at this event, such as subject treatment arm, cohort, dose, and kit number.

It can be tempting to consider building a request for randomization via the CRF and returning the information into the CRF using APIs or web services. It may be assumed this will provide sites with a simpler experience. But what if the integration fails? Many traditional EDC systems still require migrations and downtime for amendments, so what if EDC is unavailable? What if there is an outstanding shipment to be confirmed prior to randomization proceeding? What happens if a mistake needs correcting?

For these reasons, randomization should be performed directly in the Veeva RTSM user interface. It is purpose built to mitigate the risks associated with this critically important event. As with screening, data captured in RTSM can be integrated as necessary into the subject casebook to avoid duplicate data entry and reconciliation effort.

This data will vary by study design, but examples are:

- Date of Randomization
- Cohort
- Dose Level
- Stratification Criteria
- Treatment Arm

Caution should be exercised on blinded studies. Unblinding data should only be integrated if there is a definite need (for example, certain treatment arms drive a specific set of CRFs that are appropriately restricted).

Lab data, stratification scores, and other calculations

There may be data points, collections of data points or derived values that are used to determine subject eligibility, stratification or used as part of a patient's treatment schedule or dosing (e.g., weight or BMI).

These data points may reside across numerous EDC forms, such as local lab values. It is plausible to imagine the integration of these values will create more robust and efficient workflows. However, in practice the efforts for RTSM to perform lookups across data points or have an EDC system push these to an RTSM can be problematic. This is a high risk, low value integration strategy. Sites may have results available but be behind in their EDC data entry, and yet again this could result in a patient waiting incident that is completely avoidable.

This can be overcome by:

Directly entering key results or total scores into RTSM and, if applicable, integrating these into EDC

In lieu of entering lab data into RTSM, using a simple question in RTSM to confirm the patient does meet the criteria to proceed (e.g., to be randomized)

Sites do not intentionally randomize patients who are not eligible. Sponsors and vendors should trust that sites proceeding with critical transactions such as randomization or dispensation are doing so in accordance with the protocol. A simple question during the RTSM transaction to confirm that the lab values are in range, that the patient HAS met eligibility, that all procedures have occurred is preferable to a complicated integration that puts site and patient relationships at risk.

Resupply Visits

Any patient visit where a kit is allocated is a time sensitive transaction and should be entered directly into Veeva RTSM. There are some additional considerations on integrating resupply visits.

Visit event dates

RTSM records the system date and time on which the patient resupply visit was performed. The date in RTSM does not always equate to the meaning of the visit date in EDC. For example, sites may have requested a kit allocation ahead of time or it may be part of a multi-day visit. The request date may not always be the same as the dispense date.

The date of the resupply visit may be valuable to integrate from RTSM into EDC and can be used to create the visit record in EDC. However, individual study designs must be evaluated to define the meaning of the RTSM date and any date fields in EDC to avoid excess queries and data management review. Where visit schedules are particularly complex and dynamic with multiple non-dispensing visits to consider, it may be advisable not to integrate visit details at all.

Integrating kit numbers

Veeva RTSM will allocate the patient kit number(s) during resupply visits.

There is rarely value in duplicating the kit information in an EDC system. This does not drive any downstream data entry apart from supply accountability data, which is also an RTSM specific function and addressed in the next section. Therefore, it is entirely duplicative and adds no advantage to sites.

If sites make dispensation errors, there are processes in Veeva RTSM to update this sensitive information through a permitted end user or via the dedicated helpdesk. Changes to kit allocations are high risk as there are patient safety, blinding, compliance and protocol deviation implications. If these kit details are integrated into EDC the updates to these integrated fields become complicated to untangle, especially due to regulatory guidance on which users should have edit access to a CRF. It places a significant and unnecessary burden on sites.

For these reasons, Veeva RTSM recommends that kit number information be managed only in RTSM without integration to EDC.

Supply Accountability

Veeva RTSM is designed, per its abbreviation, for all Randomization and Trial Supply Management needs. Supply accountability is a key part of the end-to-end clinical trial supply management process. Veeva RTSM provides a purpose built module for the return, verification and destruction of materials at an item and content level.

The extensive workflow available within Veeva RTSM means capturing this same information in a CRF is duplicative and redundant. Full details of each return, such as the subject ID, date, amount used, returned, missing (qualitative and quantitative), verification date, destruction shipment and/or date and associated comments from the site and monitor are collected in RTSM with a full audit trail. This can be exported for any additional data review procedures in data review and reporting tools to establish any deeper IP compliance concerns, including Veeva CDB.

EDC is not designed for end-to-end supply accountability. Integrating supply accountability into EDC adds additional complexity for site users and obfuscates the accountability process. Defining it as an RTSM process provides a distinct and simple workflow for sites and monitoring teams, helping them work more efficiently and capture accurate, timely accountability data.

Withdrawal and Completion

From a site perspective, updating a patient status to withdrawn or complete does not present itself as a time sensitive transaction in the same way that screening, randomization, and patient resupply do. However, clinical supplies will continue to be ordered and shipped for that subject until the status update is made in the RTSM. To prevent unnecessary shipping costs and IMP wastage, it may be prudent to provide a simple and quick withdrawal event directly in RTSM and integrate this to EDC. Alternatively, if the EDC solution has the capability to 'push' a patient withdrawal or completion status to RTSM this could be leveraged for this particular non-critical case. The same caution should be exercised around data entry delays and EDC availability; therefore, if there are particularly stringent guidelines around IMP wastage and costs, direct entry into RTSM is preferable.

Conclusion

While the functionality and capability may technically exist in Veeva RTSM to integrate any data between any tools in any direction, the Veeva RTSM team firmly believe that simple is better. By focusing on ensuring time critical transactions take place in RTSM, the risk of urgent patient waiting scenarios is greatly minimized. By building meaningful and consistent integrations from RTSM to EDC, data reconciliation and duplicate data entry efforts can be largely prevented. By pushing back on designs considering intricate integration strategies that will put a study at risk, we are acting in the best interest of our customers.

A demonstration of our RTSM and EDC integration can be viewed here or please contact us to discuss your integration needs.