20R3 Customer Webinar Randomization

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Veeva

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20R3 Feature Summary

Sites

- Query Teams

Study Designer

- Schedule Editor
- Status - After Deployment

Rules

- Events - Did Not Occur and Change Reason
- Supported in Send Email

Admin

- Veeva Learning Integration Enhancements
- Rule Execution Enhancements
- Deployment Enhancements
- Query Team Administration
- Labs Security
- Randomization Security
- API Access Permission
- Lists the Study Role assigned to the user
- Set the Form Status for Retro Amendments
- MIscellaneous

Coding

- Batch Upversioning
- Autocoding Source
- Subject Source
- Third Party Coding Support
- Certain Coding Config moved to Coder Tools

Safety Link

- SAE Form
- First Send & Follow Up
- Automated
- E2B with ACK2

Other

- Data Model 1.0 to Data Model 2.0 Migration
- Additional APIs

Labs

- Data Driven Normals
- Visual Indicators when out of Normal Range
- Manual Override of Auto-Populated Normals
- Pre-Defined Units
- Downloaded Reference Range Template
- Analyte Library
- LOINC Code Support
- Unit Conversions
- Centralizing Tracking of Reference Ranges
- Import Lab Locations and Normals
- Reference Range Effective Dates
- Approve Lab Normals
- Approve Lab Locations
- Outdated Normals Report
- Update all Outdated Normals Job
- Pending Lab Location Report
- Update all Pending Locations Job

Randomization

- Support Different Randomization Types
- Support Diff Randomization IDs
- Amendments to Randomization for changes to Strata
- Append Randomization List for Increased Enrollment Size
- Blinded Studies
- Define Rules when Subjects are Ready to Randomize
- Emergency Unblinding
- Email notification for Unblinding
- Unblinding Report
- Treatment Reveal
- Automatic System Queries for changes to Strata variables
- Configurable manual entry of Kit/Device ID

Randomization

Randomization provides a way to randomly allocate study treatment, thereby ensuring unbiased data for statistical analysis within and across patient groups.

MARKET CHALLENGE

Medical Device companies have simple randomization needs and do not want to pay for a sophisticated IRT with robust features.

SOLUTION

Provide a free randomization tool that supports the essential functions needed to successfully randomize subjects in a medical device study.

Features: Site

Simple way to randomize	Once all defined criteria have been met, subjects can be randomized in one click. The action of randomizing is driven off of a specific permission that is assigned to the standard CRC role.
Easy access to randomization data	Once a subject has been randomized, the unblinded randomization data is available directly in the casebook view of the subject. It is also available in the Review tab.
Support of blinded data	If treatment or kit/device has been identified as blinded data, it will not be displayed in Data Entry or Review.
Support of emergency unblinding	In case of an emergency for a subject, users with the explicit “Emergency unblinding” permission will be able to reveal the blinded randomization data for a subject after providing a reason and username/password. This action will be tracked in the audit trail.
Support of treatment reveal	If a user needs to see the treatment assigned to a patient as part of their normal duties, they can be assigned the “Reveal Treatment” permission that will give them access to blinded data after entering their username/password.
Detail PDF	Randomization data is included in Detail PDF (respecting blinded data).
Kit or Device ID	If configured, kit or device ID can be manually entered for a subject.
Email notification on emergency unblinding	When an emergency unblinding is performed for a subject, an email notification is automatically sent to a predetermined list of users with the study, site, subject and time where/when the action was performed.
Automatic system queries	If a strata variable is changed after subject is randomized, an automatic system query will be generated.

Features: Studio

Enabling randomization	Once enable in a Vault, Randomization can be turned on at the study level in Studio.
Strata variable considerations	If an item is used as a strata variable, some actions will be restricted in Studio, e.g. moving/deleting the item. For codelist items, values can only be added in subsequence casebook versions.
Support in the SDS	The Randomization configuration is available in a separate sheet in the SDS.
Randomization configuration import	When creating a new study from an existing study using Randomization, the Randomization configuration can be copied (or ignored).
Rules for randomization	A new rule action is available to define when a subject can be randomized. Rules can also be written to execute after a subject has been randomized (add event group, set subject status, …).

Features: Randomization

Randomization Type	We support multiple randomization types: Simple, Block, Mixed Blocks, Stratified, Stratification with Blocks, Unequal (unbalanced)
Randomization ID	The randomization ID can be created in different ways: uploaded with the randomization list, matching the subject ID or system generated.
Collecting Kit or Device ID	Randomization can be configured to allow site users to manually enter a kit or device ID after a subject has been randomized.
Stratification	Strata variables can be chosen from all codelist and boolean items used in the schedule.
Randomization list upload	A randomization list can be uploaded after downloading a template that contains all the columns needed based on the randomization configuration.
Append or replace randomization lists	Additional records can be added to the randomization list by appending another list if the enrollment size increases. A randomization list can also be replaced to accommodate changes to the randomization scheme.
Monitor enrollment	Users with the right permission can see a list of all subjects in a study that either can be randomized or have been randomized. They can also access the randomization audit trail for each subject.
Unblinded view	A list of all randomization list records can also be displayed with the subject and treatment assigned. This view is behind a specific permission and can be used to monitor the number of randomization records still available.
Invalidating randomization	If a subject was randomized in error, their randomization can be invalidated (or “reset”) by a user with the specific permission to do so. Once randomization has been invalidated, the subject can be randomized again.

Enablement

- Randomization is not enabled automatically,
  - Must be turned on at the Vault level
  - Call Support to enable it at the Vault level

- Once enabled at the Vault level, Randomization needs to be enabled in Studio

Randomization Demo

Questions

Dedicated DEMO

For a dedicated demo of any these features,

please contact your

Account Executive OR

Customer Success Manager

Thank you