



Biostatistics Services

Veeva RTSM is a fast, intuitive and complete randomization and trial supply management solution designed to support trials of all complexities. It is modular and highly configurable allowing the expert services team to design and deliver studies with speed and accuracy.

Veeva recognizes the criticality of randomization and trial supply management and has invested in building a dedicated biostatistics group as part of our Veeva RTSM Services team. This grants our customers access to expert biostatisticians as part of every study implementation, helping to further de-risk this vital area.

Our biostatisticians work closely with the project management and configuration teams on the design and delivery of each study. They lead the randomization specification creation and offer a range of services from randomization and kit list creation through to consulting with sponsor statisticians on protocol design.

With 20+ years of industry experience, Veeva's lead biostatistician has developed robust RTSM SOPs and best practices to ensure these high-risk areas are managed with utmost rigor throughout the project lifecycle.

Benefits

- **Gain Subject Matter Expert (SME) input on optimizing study design.** Veeva's team has experience working with diverse studies, and each team member brings deep insight to various scenarios to be mindful of during development.
- **De-risk your randomization.** Our Biostatistics Team will review post-go live milestones to provide peace of mind that this critical function is operating as designed and expected.
- **Avert any potential design issues** which could affect data validity, or, even more importantly, risk patient safety if not identified.

Available Services

Randomization Lists

- Create dummy and production randomization lists to meet the requirements of your RTSM study, using our in-house validated SAS program.
- Help to specify requirements for in house lists or customer supplied lists so that they meet the needs of the protocol and the RTSM system.
- Review customer supplied lists for accuracy.
- Perform randomization milestone reviews post go live.

Kit Lists

- Create a kit list using our in-house SAS program that meets the needs of production, packaging, and the RTSM study per the agreed requirement.
- Provide leadership in the creation of the specification for the Kit List requirements.
- Advise on optimal packaging for the IMP to meet the needs of the study and the RTSM system.

Consulting

- Provide leadership on methods of randomization available that are appropriate for the study, pre and post award.
- Provide guidance on the choice of parameters for our minimization algorithm to ensure the best possible expected outcome.
- Provide simulation data to enable an informed choice of randomization method.
- Provide consultation pre and post study award on kit configuration to maximize flexibility and minimize waste of IMP.
- Help to optimize the site resupply parameters and strategies based on recruitment rates and patterns to minimize waste.

To learn more about our Biostatistical Services, [contact us](#).