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WHITE PAPER

A Proactive RTSM Approach to Trial Success

Learn how early collaboration with your vendor's RTSM experts can optimize your protocol design

Background/Situation

Working with subject matter experts (SMEs) from your Randomization and Trial Supply Management (RTSM) vendor early in the development of a clinical trial can yield results that positively influence cost and efficiency.

For example, during protocol development, a sponsor partnering with a new Contract Research Organization (CRO) might want to review initial shipment values and resupply parameters to determine pre-study forecasting estimates for packaging and labeling. They feel they would benefit from a consultation with an SME in trial supply management. Ideally, this individual would be willing to provide an opinion even if it differs from the group, stand behind it, and explain the justification.

An RTSM vendor may have this SME on their team, but an award to a vendor is unlikely to be made this early in the process, making them unlikely to provide resources.

Solution

In this specific case, the Sponsor needs a vendor with the resources to provide consultation both pre- and post-study award. This vendor should also have an experienced team that recognizes the critical areas RTSM can affect upstream or downstream and, most importantly, is willing to collaborate at this point.

Although collaborating this early can be seen as working "at risk," it also presents an opportunity for the RTSM vendor to demonstrate their team's expertise, and the value of the product and services offered.

The Sponsor learned that **Veeva RTSM** has a team of SMEs dedicated to analyzing key areas of system development and maintenance, such as Design, Project Management, Validation, and Help Desk effectiveness. This includes a Biostatistics team focused specifically on RTSM, who are willing to consult pre-study award in high-risk and high-value areas like resupply strategies and parameters. Deciding to leverage **Veeva RTSM**, the Sponsor requested a biostatistician to join a meeting to discuss their needs further. Together, they reviewed the current parameters and assumptions.

Review of the Current State

Synopsis:
A randomized, double-blind, placebo controlled study

Randomization:
1:1:1 allocation across three treatment arms:

- Low active dose
- High active dose
- Placebo

Stratification:
Stratify by site

Number of Subjects Planned:
255 subjects (85 placebo: 85 low active dose: 85 high active dose)

Enrollment Rate:
Slow enrollment

Visit Schedule:

- Screening (3 weeks)
- Baseline (4 weeks)
- Treatment (12 weeks)
  - Day 1 visit
  - Week 4 visit
  - Week 8 visit

Kit Types:
3 blinded kit types (1 per Treatment Arm)

Initial Packaging and Labeling Plan:

- Primary packaging = 30 tablets in a bottle
- Secondary packaging = 3 bottles in a carton (90 tablets total)
- Labeling = Unique numbering and labels used on secondary packaging only

Investigational Product (IP) Allocation:
1 Carton at the Day 1 visit

Subject Matter Expert Feedback

After reviewing the current assumptions for study parameters influencing the recommended initial shipment values and resupply parameters, the Veeva RTSM biostatistician began an open discussion with the Sponsor on their initial packaging and labeling plan. Considering the rate of usage and number of doses, the biostatistician suggested using packaging and labeling at the bottle level rather than the carton level, allowing bottles to be dispensed individually at each visit, rather than all at once. The biostatistician cited examples where the current plan could create drug wastage. For instance, if subjects discontinued early in the study, any unused tablets and bottles would be wasted. Similarly, if a bottle needed to be replaced, a whole new carton would need to be allocated, leading to an oversupply of bottles that would not be used.

The Sponsor agreed with this new approach to label at the bottle level. Having collaborated to optimize their packaging and labeling to limit drug wastage, the Veeva biostatistician could now also provide suggestions for initial shipment values and resupply parameters for the Sponsor's pre-study forecasting packaging and labeling estimates.

Results

By collaborating with a **Veeva RTSM** expert during their study startup process, the Sponsor was able to obtain meaningful feedback early enough to pivot their clinical supply packaging design. The open discussions fostered by this early partnership led to feedback in additional areas outside of the Sponsor's original focus, which ultimately allowed them to limit drug wastage and achieve cost savings.

This is one of the many examples of how sponsors can leverage **Veeva RTSM's** resources and expertise.

Contact us or your Account Partner to learn how you can benefit.

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