Creating a Cohort and Dose Level

Building adaptable systems to maximize study design flexibility without interruptions

A critical goal of Phase 1 trials is to establish the recommended dose and/or dosing regimen of new drugs for efficacy testing in Phase 2 trials, using a detailed and monitored dose escalation process. To reach this endpoint, study designs will have this process outlined in the protocol, including starting dose/regimen, dose levels, dosing regimen, titrations, dose escalation method, number of patients per dose level, the maximum tolerated dose (MTD) or recommended phase 2 dose (RP2D).

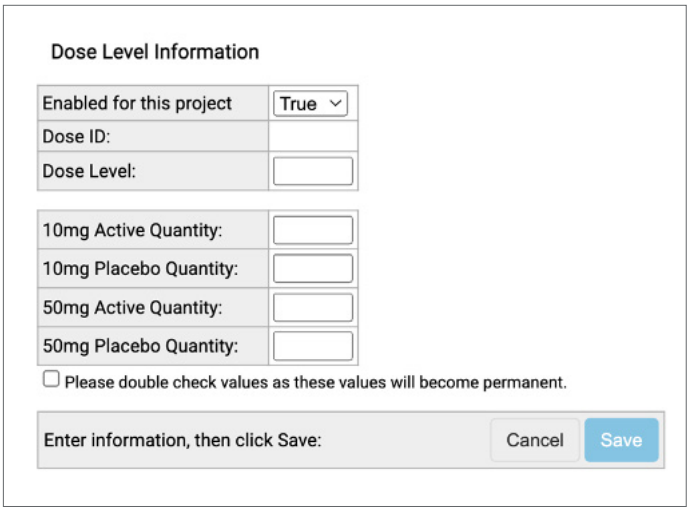
As Phase 1 trials represent the first application of a new drug to humans, the protocol will list a variety of options for each component based on the limited information available. However, the sponsor will need to continuously pivot and control how and when these components are used as the study progresses and new, more accurate data is available. Because of this free-flowing, explorative study design, it becomes exceedingly difficult for the protocol to list all the potential options that may need to be explored for components such as dose levels.

In these scenarios, sponsors require the ability to dynamically add dose levels and their associated cohorts in the RTSM to ensure their systems can change and move at the pace their operations dictate. Sponsors should be able to pivot their escalation process to areas unforeseen when the study was initially designed based on limited information. They cannot wait or rely on third party support for such changes or else RTSM could become a rate-limiting factor.

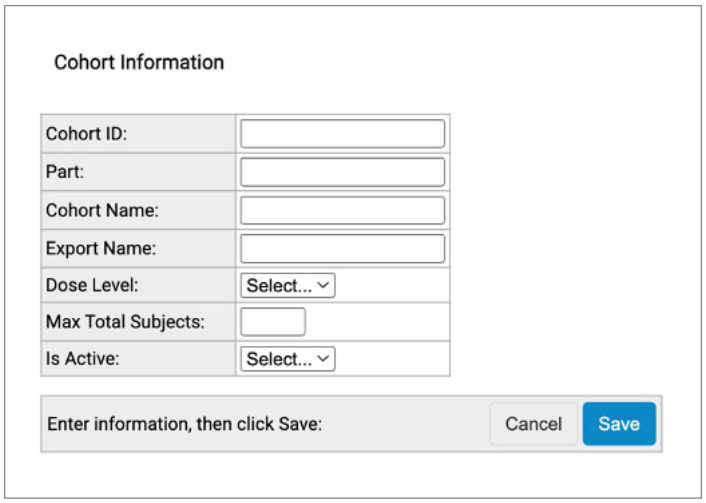
Solution

Veeva RTSM enables sponsors to dynamically add dose levels and cohorts to alter their study design based on the most recent trial data.

Users can be provided access to create a new dose level if the required level is not already built into the system. For additional flexibility, users can choose the kit types for the new dose levels when multiple kit options are available. If preferred, the system can also implement a “priority” dispensing logic, where the system will look to use an initial kit type and if it’s not available, use a secondary kit type to limit the chance of stock out (e.g. try to dispense 1 50mg kit and if not available, try to dispense 5 10mg kits). In this example, the new dose level creation functionality is built in an unblinded manner; however, this can be done in a blinded design as well.



Users can also be provided access to create a new cohort to attach the new dose level and group subjects accordingly. There is no need for placeholders to clutter the cohort management screen if or when these cohorts may be leveraged. When adding a cohort, they can have access to control all applicable cohort fields such as Cohort ID (to order the Cohorts), Part (to dictate study phase/part), Cohort Name, Export Name, Dose Level, Max Total Subjects, Is Active and any other study specific fields. Validation can be used to ensure certain fields are entered in desired formats for consistency (e.g. ensure the Cohort Name field is always entered as “Cohort X mg”). Once the dose level has been attached and a new cohort is created, patients can begin actively enrolling and progressing to the study’s endpoints.



Conclusion

Early-phase studies may have simple supply needs but require flexibility to adapt as new data emerges. Veeva RTSM adds value by enabling real-time study adjustments. In dose escalation studies, dynamic end-user controls allow sponsors to manage patient dosing levels and cohort creation without third-party support, ensuring the system keeps pace with their study operations.

To see it in action, **view our demo**.

To learn how we can help your next study, reach out to your Veeva AP or **contact us today**.