Craig Mooney,
VP, scientific eTech-enabled services, Calyx

Getting IRT Right – Part 2: Study Drug Allocation and Supply Management

In an earlier article, we reviewed the randomization risks that could arise if an interactive response technology (IRT) system isn't designed and/or implemented correctly. Here we address the consequences that trial sponsors could face if their IRT system isn't adequately designed to handle the many and often complex drug allocation and trial supply aspects of their clinical trials.

One of the primary functions of an IRT system is the allocation of drug to participants in accordance with the randomized treatment. This is a zero-error tolerance process to ensure study integrity and patient safety. To achieve success in allocation, a robust supply management system is required. Quite simply, the right medication, for the right participant, at the right time, every time. Let's explore these a bit deeper.

Like randomization, if allocation to study drug is not implemented according to the protocol the entirety of the study could be called into question. It would not be unusual given modern study designs for participants to have a crossover or other complicated dosing options. These add to the complications for implementation and ensuring the right medication maxim.

A common mistake—even made by experts—is not using the proper terminology when it comes to medication management and IRT systems (Figure 1). When terms are interchanged and conflated it leads to a lack of understanding. Not speaking in precise language can cause unnecessary complications and lead to teams drawing inaccurate conclusions. The three most often misused terms include:

Allocation/Assignment

These two terms can be reasonably interchanged. Allocation and assignment mean what the IRT system has chosen for the site to dose the participant. It is based on the study design and programmed algorithm. At the time of the transaction, it is what is intended, not what has reliably happened.

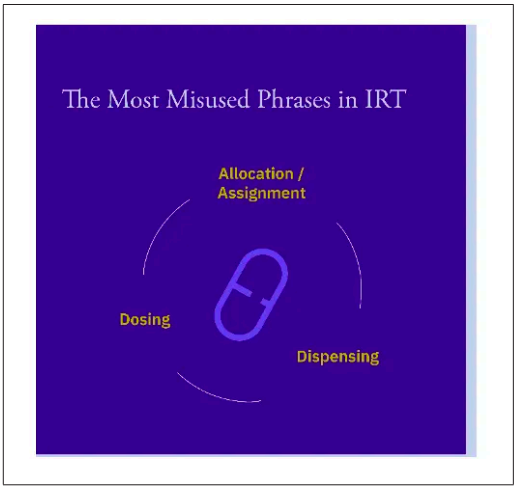

FIGURE 1. Not using correct terminology during randomization creates confusion in the IRT system and increases clinical trial error risks.

Dispensing

In a study where in-clinic dosing such as IV preparations are not required, dispensing means giving the medication to a participant to take home or, in a direct-to-patient scenario, delivering the medication to their home. This is the point when allocation/assignment turns into action. Therefore, it is improper to call an IRT transaction dispensing. Dispensing is done by study staff, not by IRT systems. Using this term conveys a level of certainty that does not exist without a confirmation transaction on the dispensation. Furthermore, it does not even confirm the participant was actively dosed.

Dosing

The final step of the process is the participant being actively dosed with the treatment. As with dispensing, dosing moves from the theoretical of what the system has assigned/allocated to a practical act performed by study staff, the medication being consumed by the participant. The IRT system does not know for a fact that a participant was dosed unless a such a confirmatory transaction is part of the IRT system design.

Data flow and reconciliation

Understanding the difference between these three distinct processes/terms puts you in a better position to comprehend what the data in each system really means. It can also guide you on the level of reconciliation required.

As one example, an IRT system can be the source of truth to ensure compliance and the most accurate data that will also support supply management. Another approach is to do only allocation/assignment in the IRT and use an EDC system to capture dispensation and dosing data. There are reasoned arguments for both. The decision is typically based on both the philosophical and practical approach a sponsor takes regarding how to manage this data flow . But whichever you choose, be precise in your language and understanding of the implications.

Supply management

Allocation/assignment will only work if the medication is available where needed. Without a proper understanding of system workflows/inputs, logistics processes, and use/availability calculations, you will struggle to meet the baseline of the right medication, for the right participant, at the right time, every time.

Complications and details related to proper supply management are so fine that they cannot be covered adequately here. But one truth about drug supply management and calculations is that it is never an understanding of the number of participants, it is always about trying to predict when and where the participants will show up.

Contact hello@calyx.ai for information on Calyx IRT.

CALYX™