perceptive™ eclinical

Reduce drug supply budget with Perceptive eClinical IRT/RTSM

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1 How IRT/RTSM reduces drug supply budget

Defining the right site supply management that lasts for the duration of a clinical trial is complex, as it relies on a range of variable factors. It can require close site monitoring efforts to react to the actual recruitment rate & ongoing patient needs. Ensuring patients can be randomized & resupplied should not result in high overage and wastage, with the associated costs those entail.

1.1 Using IRT/RTSM to manage predictable patient medication needs

Your IRT system should automatically manage each patient's medication needs that happen on a scheduled basis. As the system knows what treatment a patient is assigned, what their schedule of assessments is & their dosing regimen, it should predict exactly what medication they need & when that medication needs to be on site.

A good system should also be able to optimize supplies even when it is not known what a patient will next receive if the protocol allows dose titrations, modifications, or treatment pauses. The supply optimization should be adapted to different visit schedules, patients moving between visit schedules, skipping visits, etc., based on what the protocol design dictates.

1.2 Using IRT/RTSM to manage unpredictable patient medication needs

Some medication needs remain unpredictable, such as if & when patients will be randomized, and replacing missing or damaged medication; site supply management is therefore based on an educated guess.

Such unpredictable needs typically rely on a pre-defined amount of medication based on sites' initial expected recruitment rates e.g., low, medium, or high recruiting. These initial supplies can vary in accuracy and often remain unchanged for the duration of the study, especially when there are many sites to monitor. This leads to wastage if the values are set consistently higher than required and increases the risk of stock-outs & failed visits if spikes in recruitment are missed.

1.3 Recruitment-based site supply management

With an IRT that can monitor each site's specific recruitment, supplies to sites can be automatically adapted to reflect what is optimal for each site, to reduce both wastage and the risk of failed visits.

A good system can not only optimize site supplies by adapting automatically to each site's actual recruitment, but it also reduces the supply manager's effort by doing so.

The IRT performs a daily review of all sites to check if there are any patients 'in screening'. If the medication needs for patients' enrolment/randomization visits are not met, the system requests an appropriate shipment to those sites.

This solution can be adapted to the need of each trial; it can be used to ship medication per patient or to bundle shipments based on the current number of patients 'in screening' at sites.

A good IRT/RTSM system always considers what is present at the site before requesting a new shipment.

As medication is typically not pre-allocated to patients, if the system requests medication based on the site's actual screening rate, but the screening failure is high, medication will still get used for on-going or future patients.

1.4 Other supply monitoring uses

The above method should also be used to automatically adapt the medication shipped to sites if required based on the protocol, for example, to account for:

- - adaptive designs where a treatment arm is dropped
- - switching between local & central IMP sourcing for a country or IMP type

2 Additional ways of reducing clinical supply budget through IRT/RTSM

2.1 Adapting to patient dose changes

Perceptive eClinical uses functionality we call Fractional Prediction to reduce the IMP sent to site for potential patient titration; this is useful when the quantity or the type of IMP dispensed to patients varies based on trial requirements. A good IRT should be able to predict a fraction of each of the possible kits needed for an upcoming visit, thus reducing the overall amount sent to the site.

2.2 Shipping just what sites need for randomization

Other useful functionality is Randomization Prediction, which reduces wastage by sending IMP to each site specific to upcoming treatment group assignments when randomization codes are dedicated to the site. The IRT knows exactly which treatment groups patients will be allocated to first and can ship this specific medication to start with. Our recommendation is to ship for a certain number of randomizations at once, to reduce both the risk of unblinding and the number of shipments.

2.3 Managing medication across a program of studies

Medication Pooling reduces drug wastage and addresses drug availability concerns by sharing medication across different protocols in a single program. The IRT controls the sharing of

medication across protocols and facilitates just-in-time labeling. This method reduces the overage at the depot level and helps optimize the supply management budget at the program level rather than the study level.

3 Summary

By using the right inventory management options for your trial, you can trust that patients can be dosed without high drug wastage and its associated costs.

Perceptive eClinical's team of supply experts ran supply simulations to understand the average impact of using our inventory management options; the results showed that the more that are used, the more the clinical supply budget is optimized:

- 20% reduction in wastage with **patient prediction** compared to site buffer
- An additional 20% reduction in wastage when adding **randomization prediction**
- 40% reduction when **pooling** IMP across 3 trials & a shared depot with prediction included

Ready to find out more about what Perceptive eClinical can do for your trials – contact us for a product demonstration.