WHITE PAPER

# Main Factors that Unify IRT in Clinical Supplies

IRT has created its footprint in the field of clinical research and has evolved drastically in such a way that it has bought a major difference in perspective of clinical trials over the decades. It faceted itself into the streams from only randomizing the subject and assigning them to a treatment group to managing the overall supplies required throughout the study through supply management.

Multiple factors fall in line to manage the supplies throughout the study, where few of them are the number of subjects expected to be enrolled in each site, the number of days the shipments reached the site physically, etc. These factors help the system to develop algorithms that will monitor the supplies existing at site, supplies required at site within a month, and many more. These algorithms are more essential for an IRT system to function in such a way that there is no low stock of supplies at site. Few main facets that enable the IRT to function effectively are discussed below.

## 1. Initial ordering of Supplies

This is one of the main facets that enable the function of supply management. This facet functions through various factors like site activation, subject screening settings. The supplies shall be distributed to sites based on the predefined parameter settings given to the system.

To perform the activities of a subject, there requires a sufficient quantity of supplies. Those requirements are fulfilled by the initial shipment settings. Based on a few factors initial shipment to sites shall be raised either when the site is activated or when the first subject is screened at site, which shall prepare the site to perform the further activities of subjects screened flawlessly.

## 2. Auto Ordering of Supplies

This is one of the most important facets for managing the stock of supplies at sites. The auto orders shall be raised as on when required to meet the predictive needs and non-predictive needs of the supplies at site. These settings shall be site-specific and designed based on the parameters like recruitment rate of the site, trigger value, resupply value, check range, and the restock range.

The predictive needs of the site are fulfilled through predictive settings given to the system. The System shall check the values given and raise the shipment accordingly with the required quantity of kits with kit types from the lots.

The non-predictive needs of the site are fulfilled with the buffer settings given to the system. System shall raise the shipment according to the values provided.

This way the IRT functions effectively to maintain the supplies at each site.

## 3. Safety Settings

These settings play a vital role at supply level and site level. These settings are designed in such a way that the expired supplies are not reaching the subject in any way. Maintaining the expired supplies and shipping them is a waste of resource, time, and cost too.

Each shipment is very important and it shall be planned in such a way that the budget of the project does not affect in any way. These safety settings and auto-order settings shall add value to the tool in customizing the shipments as per the requirements and unnecessary shipments are not raised.

The shipment or dispensing of the expired supplies is halted with parameters like DND (Do Not Dispense), DNS (Do Not Ship) & DNC (Do Not Consider) which are core terms in IRT.

## 4. Site Activation

This one of the core steps to be performed, as all sites, shall not be activated at a time. As per the regulatory and the success of SIV a site shall be activated. This action requires authentication as there shall be an initiation of supply to the site once it is activated.

Once the site is activated, the site shall be enabled for the screening activities, randomization activities, and supply-related activities. The Site needs to be configured with all the data as per the protocol before activating.

Once the site is activated, the system shall raise the initial shipment as per the settings provided, the request of the shipment would include the number of kits from the defined lot, expiry date, site details so that the supply manager shall record all the data and ship the required kits physically. Supply activities of the site include the acknowledgment of shipment once received at site.

## 5. Tracking of the supplies

Tracking of supplies is one of the main focus points of IRT. Even though it does not track the live movement of the supplies, there is a passive way of tracking which shall deal with the change in the status of the supplies as when required.

The System shall have a different status for the orders and the kits. These statuses shall be permission-based and only the desired personal shall change the status so that it is recorded and tracked in the system.

## 6. Multiple depots and sites shipments

The distribution of supplies in a clinical trial is not only defined for a single site or depot, it involves many sites and depots. It can be both depot to depots, depot to sites. Each site shall be assigned to a depot for supply-related activities. The supplies for that particular site shall be maintained by that depot which shall be easy for tracking and resolving any issues related to supplies.

The depots shall be maintained with sufficient quantity of IP's throughout the study to meet the requirements at the site. A line of authorization is built in while shipping the supplies to sites as not all sites require the supplies as generated by the settings provided for the system. This line authorization shall check and cross verify the requirements with site and approve the shipment. This level shall not allow the overflow of supplies to sites when there is no such requirement.

There shall always exist the physical shipment of supplies from the sites with overstock to the site having low stock. This physical shipment shall be tracked in the system with a functionality called 'Return to Depot' where the sites with overstock shall return the supplies to Depot and the shipment shall be generated from the site with low stock. This feature helps to manage the supplies without any further demand in the production.

## 7. An Eagle Eye – Audit Trail

It is mandatory for a trial personal to know each and every aspect of the study regarding the activities of site, depot, kit, users. This will always help the administration team to view the status of the study and monitor the pros and cons during the study conduction.

The audit trail is designed in such a way that an administration team can filter and know the activities by user wise, site-wise, depot wise, and the status and history of kits as well.

## 8. Data Visualization through Dashboards and Reports

There shall be many factors to be focused on throughout the conduction of the study. These parameters shall be monitored easily when their status is displayed on the dashboard and the data is projected in the form of reports.

The pending visits of a subject can enable the administrator to plan the resource and check the supplies at site. The summary of orders on dashboard also helps the trial team to track the supplies.

The reports should be developed in such a way that it gives the complete overview of the study in terms of the sites, depots, kits, visits, etc. It should be easily accessible and user-readable.

The events and alerts shall be shared with the desired team as on when required in the form of notifications and are one of the other best ways to inform the status of the study being conducted.

IRT is recognized as the realistic data provider so that it can be integrated with other tools like EDC and CTMS as a source data provider. The evolution of IRT is not defined to a certain point, as the designs of the studies increase the evolution and the facets of IRT also increases.

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