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# Water Cooler Chat

# Optimizing IRT for Clinical Supply Management

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**PCI Clinical Trial Services hosts a biweekly virtual *Water Cooler Chat* series, where our subject matter experts host informal discussions around a number of clinical supply hot topics.**

# Optimizing IRT for Clinical Supply Management

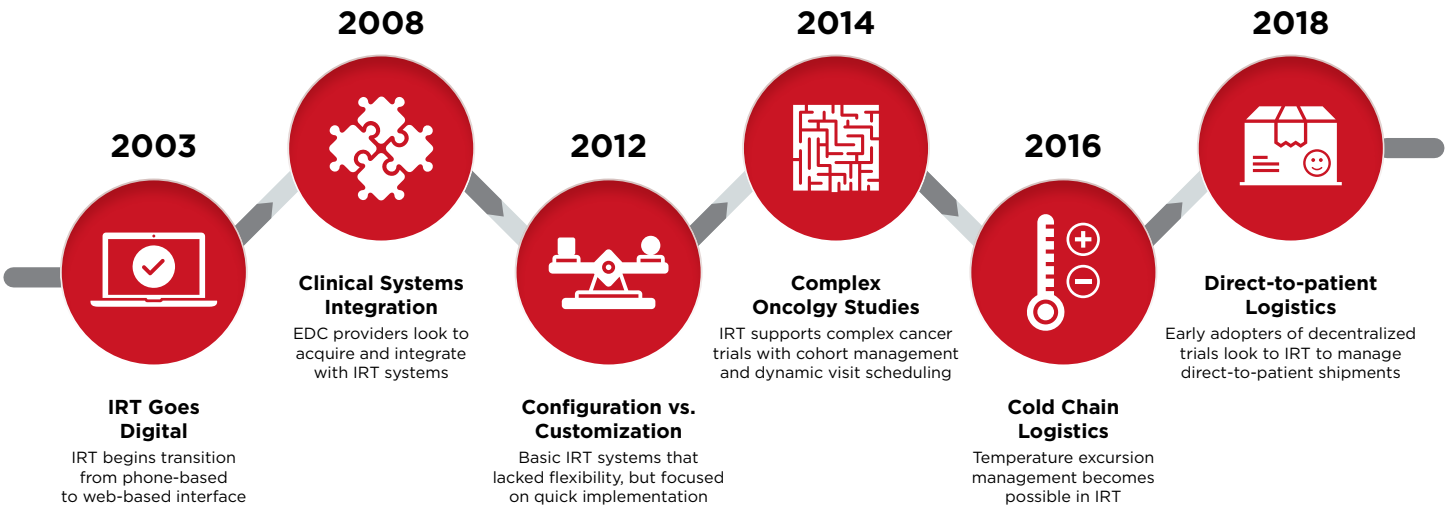
**Laurel Ferenchick, PCI's Senior Clinical Supply Manager and Marc Lisi, Suvoda's Co-founder and Director of Business Development recently spoke on the various supply capabilities within IRT.**

**Laurel and Mark explained what to ask for and who to involve when developing a list of needs for an IRT system to optimize the clinical supply chain. They described ways that flexibility is important to functionality, such as drug resupply settings, initial shipment triggering, and direct-to-patient logistics. And when figuring out what questions to ask in optimizing IRT for clinical supply, they suggested scenario planning as it relates to study protocols, priming professional networks for information on solutions, and being up front with IRT vendors on needs and nice-to-haves.**

In all facets of clinical development, whether it is trends that have surfaced over the years or the unpredictability of individual protocols and study data, things are subject to change swiftly, sometimes without precedent, and at times without warning. This is certainly true more specifically in managing the clinical supply chain.

Interactive response technology, better known as IRT, has become a way for sponsors to execute increasingly complex

**Timeline indicating some of the most recent innovations in IRT, and how clinical supply has become increasingly involved**




trial designs. More specifically, it has evolved alongside the clinical supply chain since its origins in the 1980s as a way of syncing up randomization of patients with the allotment of drug kits at sites. In aligning patient logistics with clinical supplies, sponsors have been able to more efficiently allocate drug supply to sites to reduce costs and time. As a result, the level of control and customization that sponsors have in IRT to direct clinical supply flow has reached a point of sophistication that requires a thorough degree of understanding.

## Who to Involve in Specification Development for IRT

Studies continue to become increasingly complex, and the capabilities continue to move in tandem with these complexities. As IRT systems have added and scaled capabilities, study teams require closer collaboration with vendors in designing systems that incorporate the latest efficiencies to address drug and patient logistics.

In developing specifications for an IRT system, an all-hands-on-deck approach is crucial to create a well-rounded system that sufficiently addresses each study team member's needs. Clinical Operations is a necessary party to ensure a system handles critical patient logistics such as visit scheduling. Since patient logistics and other clinical operations-related specifications can affect supply chain, drug supply managers also need to be involved in specification discussions. This can ensure that efficient supply workflows are thought out and all corresponding functionality is built into the system. Biostatisticians should be involved in the design of IRT builds for any randomized trial, regardless of whether a study calls for centralized or global randomization, or when it incorporates stratification and cohorts.

## Functionality to Optimize Supply Flexibility

Flexibility is valued above all else to meet ever-changing needs within a study, regardless of how specifications are developed for an IRT. Below are some ways that flexibility can be built in to optimize supply management.

**Temperature Excursion Management**

IRT has long been used as a tool to oversee drug accountability. As such, it makes the most sense for clinical supply teams to manage temperature excursions within an IRT system. Since this development, IRT has increased visibility considerably for clinical teams to more effectively

monitor temperature-sensitive products. These systems can integrate with sensors and software that measure deviations from specified temperature windows.

Clinical supply managers can automate the quarantine of drug kits within IRT systems when the kits deviate from specified temperature parameters. They can also automatically notify teams when drug is quarantined in the system. This temperature excursion functionality is useful, not only in managing shipments to sites, but also at the site level where the supply manager can help with the disposition of material.

**Initial Shipment Triggers**

Clinical supply managers can examine the study protocol to determine the most sensible event to trigger shipments to start flowing into sites. For studies that recruit patients quickly within a given period of time and have investigational product (IP) with a more durable stability profile, it may make sense to trigger initial shipments for sites when they are first activated in the IRT.

But studies with longer run-in periods or with sparser recruitment for patients over time may require another strategy. Initial site activation as the initial trigger in these cases may incur unnecessary costs through the deployment of product that is not able to be utilized quickly enough. If a study has a large window between screening and randomization with a high screen fail rate, it may be best to set the initial shipments to not trigger until the first subject is successfully screened to avoid drug sitting idly at sites.

**Cohort Management**

Early phase oncology studies often use cohorts as a way to effectively establish which types of patients are finding the most therapeutic value. It is important that IRT can handle the addition, subtraction, and modification of cohorts as needed to help sponsors maintain flexibility in early phase studies and beyond. For that matter, systems need to be able to handle fluctuating patient numbers and possible expansion into open-label studies when necessary.

**Resupply Strategy**

Controlling the size and timing of resupply shipments to sites is integral to optimal clinical supply management. As

patient enrollment often varies by sites, having a system that can allow drug supply managers to update site resupply settings as needed can reduce drug wastage. Since lead time to sites and country-specific requirements can vary widely, so too can resupply strategy. IRT systems that allow users to create different resupply groups by site, region, or country can be helpful in accounting for these variations more easily.

Changing particular settings for resupply groups, such as the minimum and maximum parameters (these limits are labelled differently across IRT vendors) allows for flexibility where it is needed. Flexibility is also needed in accounting for longer shipment times to sites that are further from central distribution. As such, systems can structure in additional 'do not ship' or 'do not count' times to account for longer lead times to sites. This ensures the end goal that patients never miss out on a dose.

Predictive resupply abilities can help supply managers account for future dispensation dates. After an initial shipment is triggered, automated resupply shipments are sent to the site to account for upcoming patient visits and unexpected needs. As predictive resupply can accord with resupply groups by site, region, or country as described above, different levels of enrollment across these dimensions can be taken into account.

Some IRT systems have an alternative buffer feature where systems automatically switch over to new minimum and maximum parameters for resupply at a certain point. An example is when a site hits its enrollment limit or a study decides not to enroll new patients. The system automatically switches over from the regular buffers to the alternative to prevent the generation of automatic shipments of drug to sites that are never going to be used.

**Direct-to-Patient Logistics**

Over the past few years, decentralized trials have gained traction as a way to accommodate smaller patient populations with limited ability to access trial sites, or patients who live far from sites. More recently, safety concerns arising from the COVID-19 pandemic have furthered the need for such functionality in clinical trials.

While the need for direct-to-patient logistics may be clear, there are many nuances involved that call for upfront expertise and/or flexible systems capable of addressing them. Most obviously, having direct-to-patient as an option can be a safeguard for trials. The flexibility to turn direct-to-patient functionality on and off in IRT is great for those sponsors who feel they might need it to account for low enrollment rates, patients who live far away from sites, or as a safety precaution for subjects who are immunocompromised or otherwise have comorbidities that exacerbate the risks of infection.

Since IRT facilitates the initial prompting of a direct-to-patient shipment, one common concern is that systems are a risk in terms of storing sensitive information such as a patient's address. Systems are designed to account for this, and instead use a unique patient ID number to communicate to the courier or depot vendors who need this information to ship to patients.

Additionally, IRT accounts for potential unblinding scenarios common to direct-to-patient shipments. For cancelled shipments, drugs are automatically marked 'temporarily unavailable' in the system instead of being automatically reassigned to another patient. This ensures that blinded users cannot learn that two patients are receiving the same treatment. To prevent unblinding when raising ad-hoc shipments, an IRT system automatically raises a shipment containing the appropriate drug types according to the unique patient ID without revealing the patient's treatment to the site user.

While some studies will send drug exclusively direct from depots to patients, other studies will need to account for variations across regions and countries where regulations do not allow this. Allowing studies the flexibility to send from a central pharmacy directly to patients, or from sites to patients as needed will account for these geographic variations in regulation. Studies running a hybrid model will need to be able to control this functionality at the site level. They may even need to offer this control on a patient-by-patient basis, as some protocols allow patients to opt in or out of a direct shipment option. Determining what kind of flexibility a system needs up front in this regard will ensure study teams can optimize their IRT for a variety of potential scenarios.

**Reporting**

Report building functionality can be useful in IRT to ensure compliance and inform sensible supply strategy. A tool such as an ad-hoc report builder can give sponsors access to their data in real time and save them time compiling the data manually through spreadsheets. Access to data and reporting is even more important with direct-to-patient studies since teams are managing dispensation, clinical outcomes assessment, and other processes remotely.

In many cases, sponsors do not have access to their data in IRT when they need it. It is very critical to discuss this feature with an IRT provider up front. It is not recommended to wait until the system is live to then figure out what type of reports are needed. A good IRT provider should be able to build any type of report required and have real-time information available.

## IN CONCLUSION

IRT has proven to be an integral solution for sponsors and clinical teams when looking to simplify their increasingly complex studies. As such, upfront planning can empower clinical supply teams to optimize clinical supply chain in as many scenarios as possible. While the temptation to release an IRT system piece by piece may arise, this could set a study up for increased risk exposure.

If the ever-shifting landscape in clinical development were not enough, the global pandemic has become a stark reminder to clinical teams that planning and adaptability are key. Planning up front means knowing what questions to ask. For those clinical team members who are unsure of what to think about when approaching IRT, it is recommended to plan for scenarios related to the study protocol at hand. Lastly, they should provide as much information as possible to an IRT provider to meet all possible needs and ensure a good experience.

**About Laurel Ferenchick, Senior Clinical Supply Manager, PCI Pharma Services**

Laurel Ferenchick is a Senior Clinical Supply Manager at PCI Pharma Services. She has over 14 years of experience in clinical trials with a background in packaging, logistics, IRT, and supply chain management. She earned an MBA in pharmaceutical business from the University of the Sciences in Philadelphia. Laurel currently lives outside of Philadelphia with her husband and 2 sons and enjoys geeking out with Legos, Harry Potter, and Star Wars.

**About Marc Lisi, Director, Business Development, Suvoda**

Marc has spent his entire career in the eClinical technologies space, with most of that time focused in the area of IRT. Having spent years on the client services side, Marc has worked with 7 of the top 10 pharmaceutical companies and 6 of the top 7 CROs to design, implement, and maintain IRT solutions across a variety of therapeutic areas. As a Co-founder and Director of Business Development at Suvoda, Marc uses his IRT subject matter expertise to provide creative solutions to customers' problems, all while growing Suvoda's business globally. Marc enjoys creating long-lasting relationships with customers and colleagues and loves brokering introductions within his network. Having graduated from Lafayette College with a degree in biochemistry and minor in music, Marc enjoys cooking and traveling with his wife.

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