CALYX™

CASE STUDY

# Calyx IRT: Ensuring Trial Supply through Unexpected Study Changes

## SITUATION

Calyx IRT was the system of choice for a study involving patients admitted in intensive care units (ICU) due to complications linked to COVID-19 infection. The study was run through a CRO, and Calyx worked directly with both the CRO and the sponsor team.

On paper, the study was a relatively simple IRT design, investigating whether the study drug would reduce the time spent in ICU. Patients were enrolled in the study upon admission, treated in the ICU, and dosed up to 6 times over the course of 28 days or until discharge, whichever was earliest. There was an established depot network from the study start and supplies to sites were based on expected recruitment rates.

However, clinical trials rarely go to plan, do they?!

## CHALLENGE

During trial execution, the sponsor had to switch distribution vendors, as they were not satisfied with the one selected initially. The switch had to be done in flight, while sites were still recruiting, without impacting supplies to sites and patient recruitment.

For the last 10 months of the study, the sponsor faced a critical situation regarding medication management. Due to a longer start up period than initially expected the medication in stock at depots and sites was about to reach expiry limits. Without any additional stock and no time to manufacture more medication, they risked not being able to supply patients with medication, which would have resulted in the trial closing before reaching the required sample size.

## SOLUTION

The Calyx project manager leveraged their experience managing similar situations to address the challenges the sponsor faced.

### SWITCHING DISTRIBUTION VENDOR

Calyx IRT includes standard integrations for both distribution vendors that were used in this study. Switching vendors mid-study required changing the depot network, as well as applying different integration standards, to support ease of use for the new distribution vendor.

Thankfully, Calyx IRT inventory management includes flexible settings made to deal with unforeseen situations like this one. We used those settings to increase the stock of medication at sites, anticipating that stocks would need to last longer during the depot transition period.

We supported the clinical supplies team with transferring medication to the new depots and releasing the medication for use once it was confirmed to be available at the new depots. The depot transition and new integration were invisible for sites.

The Calyx project manager was instrumental in advising the CRO and sponsor how to navigate this situation, recommending the most suitable options available. They coordinated the various updates required and released them all at the right time, in alignment with the physical move of the medication stock.

### USING MEDICATION CLOSE TO EXPIRY

Situations where medication is reaching expiry dates are tricky. Calyx IRT inventory management includes flexible Do Not Ship and Do Not Dispense settings, which can be amended down to patient dispensing level if required. We would usually recommend not amending those settings, but our team has the right level of expertise to implement those updates safely.

For this study, the Calyx project manager worked closely with the clinical operations team whenever a patient needed medication. This included actions to ensure that patient status within the IRT were proactively updated to reduce the risk of predicting too much medication, therefore increasing accuracy of shipments. They demonstrated excellent communication and prioritization, ensuring inventory management settings were amended immediately and appropriately to allow medication dispensing to patients. The Calyx project manager kept the study team informed throughout the process, allowing the team to set expectations with monitoring and site staff.

## RESULT

Thanks to Calyx's flexible technology and excellent project management, the sponsor was able to recruit the number of patients they needed and dispense medication to those patients without putting their safety, or the trial, at risk.

The trial was a success and supported the sponsor's request for Emergency Use Authorization from the FDA for the treatment of critically ill COVID-19 patients.

Book a meeting to learn how Calyx IRT can tackle your RTSM challenges and drive your trial's success.

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