COVID-19 COMPENDIUM

WHITE PAPER

Strategies for Continued IRT Success During COVID-19

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This informational white paper is part of a compendium intended to share best practices and ongoing learnings related to the impact of COVID-19 on ongoing and planned clinical trials. Content is authored by a dedicated team of experienced scientists, clinicians, technologists, and data quality experts. To read other white papers in the series, please visit **www.signanthealth.com/covid**

WITH THE RAPIDLY EVOLVING NATURE OF THE CORONAVIRUS (COVID-19) PANDEMIC, CONFIGURABILITY AND ADAPTABILITY ARE KEY FOR IRT SYSTEMS IN ORDER TO MINIMIZE THE IMPACT TO CLINICAL TRIAL PATIENTS. OVER THE PAST FEW WEEKS, SIGNANT HEALTH HAS MET WITH SEVERAL CUSTOMERS TO HELP THEM MITIGATE THE INCREASING CHALLENGES AND AVOID INTERRUPTIONS TO THEIR ONGOING TRIALS. NOW, WE'RE SUMMARIZING OUR FINDINGS AND BEST PRACTICES BELOW, IN ORDER TO SHARE WITH THE INDUSTRY AT LARGE.

DISTRIBUTION CHALLENGES

It seems that every day there are new distribution challenges for sponsors to address. Some of the most common issues are related to import delays due to closed distribution routes. These types of shortages require sudden changes to how sites are supplied. For example, if a depot in another country can import an item easier than your current depot, this should be quickly updated in the IRT. Making these updates so may require the addition of the new depot in the IRT, moving the medication, or more. Regardless, this must be communicated to your IRT provider as soon as possible.

A longer-term solution to prolonged import issues is to add a new sub-depot within an impacted country. The new sub-depot could be a local pharmacy that has the ability to ship to sites within a region to avoid delays with customs or country import requirements while still considering all local pharmacy regulations. With this strategy, larger shipments can be sent to the new sub-depot to supply all the associated sites. This is similar to a central pharmacy design, but instead of requiring the sub-depot to ship for each patient visit, it would ship for all visits at a site within a set window of time.

In instances where a site is no longer able to dispense medication to patients, IRT resupply logic for the site should be quickly disabled to conserve supplies at the depot. Within the IRT system, threshold and/or predictive resupply logic to individual sites, specific countries or for the entire protocol can be turned off to limit the amount of resupplies sent to sites. These changes take effect immediately and manual shipments can still be created using the end user interface to accommodate special circumstances.

Supply chain management parameters should also be reviewed to ensure that they align with current distribution challenges. With patients possibly taking home multiple visits worth of medication, IRT settings must account for the additional time the medication is with the patient. In addition, the resupply triggers surrounding resupplies for expiring medications may also need to be adjusted to allow more time. As distribution becomes more challenging, study medication shipped to a site should have a longer shelf life to limit the amount of resupply shipments required due to expiry. The IRT can also help manage relabeling at the site to extend the expiry and ensure sites are using as much of their existing supply as possible.

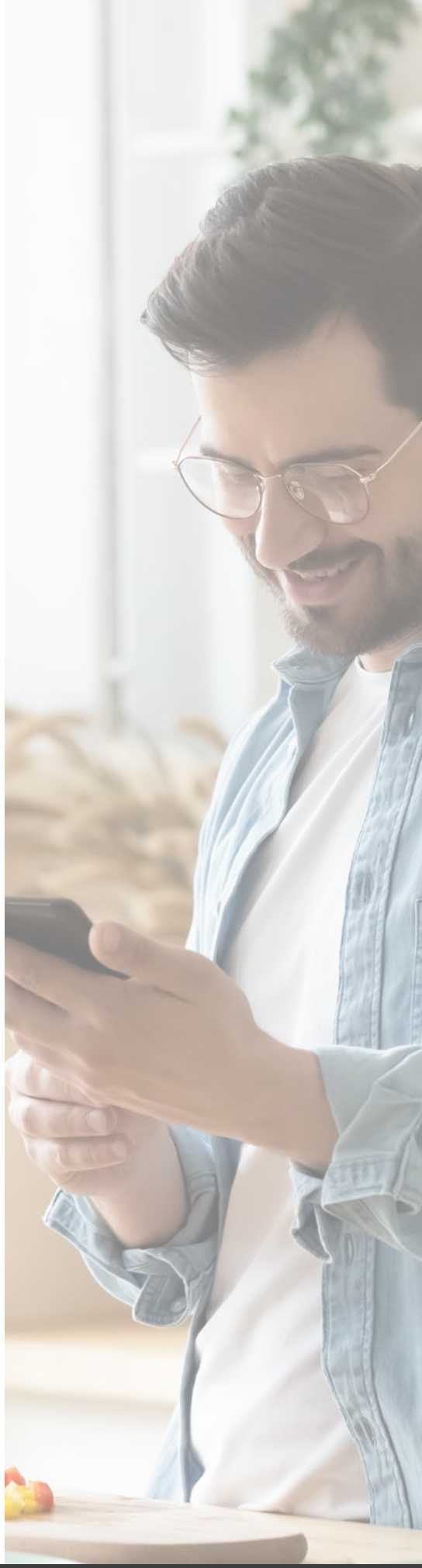
SCREENING AND ENROLLMENT CHALLENGES

While updating the supplying depots or turning off resupply logic will help address distribution challenges, there may also be logistical challenges for patients attending site visits. There are many options to address this within IRT. The first option is to supply the patient with additional study medication so that they will not need to return to the site as often. This option is highly dependent on the way the study medication is administered and other protocol requirements (e.g. dosing, storage requirements, shelf life, monitoring, etc). However, if it is an option there are simple changes that can be made in the IRT to simplify this process for sites. This includes extending the predictive look out windows and increasing the threshold amounts so that the sites are provided with extra study medication to give to patients. Strategies like these must be coordinated with site staff, as they will need to record several visits in a row for the patient in order to permit the patient to take home the additional medication. If the system restricts the time between visits, unscheduled visits can be recorded to supplement the patient's take home medication. Alternatively, the IRT can change hard visit windows to soft visit windows for patients in order to reduce the number of protocol deviations.

In addition to supplies, patients can also be moved to other sites to allow them to continue their visits. Within the IRT, the patient can be associated to a new site along with their visit history so that they can continue their treatment without interruption. Another option is to implement a central pharmacy design where the 'parent' site is the study site and each 'child' site is a patient. To maintain patient confidentiality no Protected Health Information (PHI) should be entered into the IRT. This configuration would be another approach to implementing Direct to Patient (DtP) shipments in the IRT.

We've heard that several studies are suspending screening and enrollment while allowing current patients to continue their treatment. To facilitate this, IRT systems can be used to quickly turn off screening and enrollment at the site, country or study level. To conserve supplies in these circumstances, sites can be switched to a predictive-only resupply algorithm. This would limit the stock at site to only what is needed for the upcoming visits, and any buffer stock would be depleted as patients need additional, unscheduled or replacement medications. In addition, one-time manual shipments can be sent to resupply any site that exhausts their buffer supply.

Lastly, as mentioned earlier, organizations can update their IRT's predictive algorithm to look for longer periods of time in an effort to account for more upcoming visits and create fewer, yet larger, shipments to the site. If certain countries or sites are consistently using more of their buffer stock than expected, the predictive check can run more frequently to mitigate the risk that the site will not have the necessary supply for a patient.



IN SUMMARY

While the Coronavirus (COVID-19) pandemic continues to strain clinical trials worldwide, a properly configured and adaptive IRT system can enable organizations to stay flexible and agile amidst a growing number of challenges.

As always, any changes in the IRT should always include cross-functional input from the clinical team including Data Management and Statistics. Signant Health has a team of IRT designers, developers, supply experts and statisticians who are available to help consult on various study options to help support your clinical trial during these unique times.

WHO IS SIGNANT HEALTH?

The best technology succeeds in the background. Signant Health provides solutions that simplify every step of the patient journey to make it easier for people to participate in, and for sites and study teams to run, clinical trials. Signant unites eCOA, eConsent, Patient Engagement, IRT, Clinical Supplies and Endpoint Quality into the industry's most comprehensive patient-centric suite – an evolution built on more than 20 years of proven clinical research technology. Our intense focus on the patient experience, deep therapeutic area expertise and global operational scale enable hundreds of sponsors and CROs (including all Top 20 pharma) to extend the reach of drug development, expand patient opportunities and improve data quality – helping them bring life-changing therapies to our families and communities around the world. Take a significant step toward patient-centricity at signanthealth.com.

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