

A two-month lockdown in Shanghai

Almac's creative solutions overcome drug supply, administration, and forecasting challenges



During April and May of 2022, Shanghai, China's economic center and home to 25 million people, was on "lockdown." Residents were confined to their homes for two months as part of the country's zero COVID policy aimed at preventing the spread of the virus's Omicron variant. This measure meant that clinical trial participants were unable to visit sites and that investigational products (IPs) could not be shipped from depots to trial sites.

The challenge: Trials in progress within a city on lockdown

When the lockdown was announced in Shanghai, approximately 15 of Almac Clinical Technologies' clients were in the midst of conducting clinical studies in China. While each of their situations was unique due to the nature of their protocols and the status of their studies, all turned to Almac for proposed solutions. How could they ensure treatment compliance and prevent any detriment to subjects' health in the face of such unusual circumstances?

The solution: A range of creative work-arounds

Almac proposed a number of different solutions, each geared to a given client's situation and designed to present the lowest risk of impacting blinding, data integrity, and patient safety. The options included:

- Temporarily increasing sites' drug inventory. In those cases where lockdown plans were announced in advance and where sites' storage space allowed, one solution was to increase sites' inventory of the IP. This gave sites a higher buffer of drugs on hand to tide them over during the lockdown. Almac would work closely with the client to translate future site needs from the IRT's predictive supply algorithm into manual drug orders. This would involve temporarily extending the projection window in Almac's IRT, IXRS®3.
- Transferring subjects to other sites. In situations where a site's supply was depleted during the lockdown and where subjects were still mobile, Almac recommended that the subjects be temporarily transferred to another site located outside of the lockdown zone. Thus, the subjects' treatment would be unaffected by the inventory shortage at the original site. IXRS®3 could support such transfers immediately and seamlessly, avoiding any disruption to patients' treatment.
- Dispensing comparator medications at local pharmacies. In open-label studies, Almac suggested that subjects might receive the comparator drug from the local pharmacy. In this situation, the corresponding drug assignment visits that would normally be recorded in IXRS®3 would be skipped, and a note would be raised in the file to detail why drug dispensations were not complete in IXRS®3 as expected.

One sponsor was able to apply this option to a particular lung cancer study that Almac was managing as the trial drugs were available to be dispensed from the local pharmacy. However, the IRT system was, of course, not able to capture the drug dispensation. Nor could it project the supply needed for future visits. This was an important consideration, as the drug would eventually be sourced by the sponsor once the lockdown had ended.

Almac anticipated this challenge as part of the initial risk assessment of the solution and prepared for it. Once the lockdown was over, a report was created for those subjects whose drug assignments were made outside of IXRS. The study monitors then worked with sites to raise manual orders for the first assignments post lockdown. Once a record of the subjects' kit assignments was again captured in the system, supply projections continued as usual.

- Shipping drugs directly to patients. Almac proposed that, under certain circumstances, the IP be shipped directly to the subject's home. This solution was workable only when the use of the IP did not require training or when the subject/caregiver was already trained on how to use it. Also, the IP could not be a controlled drug, and there also had to be a courier service available to collect the kit from the depot and deliver it to the subject's home.

The Result: Minimal Disruption

The Shanghai lockdown impacted approximately 50 studies that Almac was managing at the time, and by working closely with the sponsors, Almac was able to minimize the impact of the unprecedented situation. Subjects were able to continue their treatment, resulting in study compliance. Once the temporary workarounds were no longer needed, Almac's IRT system, IXRS, was able to resume normal operations of recording drug administration and projecting for subjects' future supply needs.

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