ALMAC

Partnering to Advance Human Health

Case study

Political disruption risks loss of access to comparator drug

Political disruption poses accessibility risks to comparator drug for phase II open label study

There is a lot that sponsors of clinical trials can do to mitigate the risk of delays and disruptions and safeguard clinical supply to patients. From considering labelling requirements at a study's planning phase to ensure a fit-for-purpose, compliant strategy, to embracing cutting edge technology and expert consultancy to effectively forecast demand and minimise waste.

Yet factors outside of a sponsor's control can sometimes emerge that heighten the risk of costly delays that have the potential to negatively impact patients and test the resilience and agility of sponsors. When trials involve multiple study centres and span several countries, the impact of such events is magnified; seriously compromising a sponsor's ability to meet core study milestones and safeguard patient experience.

When sponsors are at the mercy of third-party suppliers and wholesalers, in unfamiliar markets and sometimes volatile countries, identifying appropriate comparator supply solutions is a critical aspect of clinical trials management that can protect against unforeseen problems.

It is difficult to foresee all possible eventualities but when situations outside of a sponsor's control unfold that compromise access to vital comparator products the success of a trial is put in jeopardy. In these situations, there are various options and strategies that can mitigate the impact and assure supply.

For one sponsor operating a phase II open-label study, political disruption in the comparator drug supplier's country caused an immediate and indefinite supply block.

The challenges

Complete break in comparator supply chain threatens continuity

The sponsor's single-arm, multicentre trial was designed to assess the efficacy of the investigational product, in patients with a specific type of blood cancer, against the market leading, commercially available drug.

The sponsor outsourced comparator sourcing for the commercial drug, along with clinical labelling and distribution functions, to Almac Clinical Services.

Mid study, political turbulence in the country where the comparator product had been sourced made it impossible for the Marketing Authorisation Holder (MAH) to maintain its supply agreement. Due to political pressures, the MAH were required to ensure drug availability and access to patients within the domestic market. This meant that they could no longer supply the product to external markets for use within clinical trials. This included supply to Almac for the sponsor's trial.

Understanding the significance of delivering drug supply continuity to the sponsor's patients, Almac's team of procurement specialists began a race against the clock to implement an effective planned back up supply strategy.

The Almac solution

Rapid response and global network secures replacement supplies

With over 30 years' experience in managing clinical supply chains on behalf of sponsors, Almac was able to utilise its network of globally approved suppliers to establish an alternative solution.

Almac's procurement specialists harnessed their strong, professional relationships within the supplier community and identified an alternative supply of the drug from a different source country. In doing so, Almac was able to submit a targeted enquiry to a strategically positioned supplier and receive a positive response to supply availability within a very short timeframe.

The results

Trial continues without delay or negative patient impact

Thanks to Almac's coverage of key global markets and expertise in comparator sourcing, a suitable alternative was identified with near immediacy. In fact, the product was sourced, ordered and delivered before any impact to the trial occurred.

Due to the team's responsive and agile intervention, a replacement supplier was successfully secured before the risk posed by the pending break in supply had the chance to escalate.

Instead of taking a problem to the sponsor, Almac was able to proactively resolve the issue and provide reassurance that a solution was already in place.

By searching the global marketplace to source the same comparator product via a new supplier, rather than opting for a more readily available yet different comparator drug product, the need to re-submit the study for approval was avoided. As such, delays – and additional costs – were minimised and patients' treatment schedules unaffected.

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