
Beating the Clock: How TecEx Medical Ensures That Clinical Trials Start Without Delay

Time is precious, especially in the case of clinical trials. It's not just a matter of making sure the trial starts on time but also ensuring that all the commodities are at the site, all the correct documentation is up to date, and the proper authorizations have been given.

All in all, this is a gargantuan task. With various moving parts and tight deadlines, having a partner to assist with the global logistics of your clinical trial commodities is essential to your supply chain.




Tight deadlines

Meeting the Site Invitation Visit (SIV) date is the most crucial of all the deadlines in a clinical trial. This is the date the site is approved to commence the study.

All pre-study compliance, such as ethics approval, must be given for this to happen. Also, all the commodities required for that study must be present at the site. This includes any investigational product (IP) and ancillary equipment (non-IP). Again, this must be in the correct volumes required for the study.

What is done during an SIV?

- + The IP and required non-IP is on-site and ready
- + All source and regulatory documents are detailed
- + Ethics approval is confirmed

The Unique Challenge	Time Crunch for a Clinical Trial	Accelerated Customs Clearance
 <p>A leading global Sponsor reached out to TecEx Medical to assist with a time-sensitive shipment.</p> <p>Printed patient materials needed to be sent to the clinical trial site from the United States to Canada. However, the bio-pharmaceutical company was still awaiting ethics approval, and the SIV date was only weeks away.</p> <p>As one of their numerous and concurrent clinical trial studies occurring across the globe, the Sponsor was under immense pressure to get these materials to the site on time.</p>	 <p>With the rapidly approaching SIV date, the TecEx Medical team with oversight from the Sponsor immediately began the process by directly reaching out to the vendor involved.</p> <p>TecEx Medical liaised with this vendor to obtain outstanding information for customs approval. This was done so that the materials could quickly be shipped once the ethics approval was granted.</p> <p>In-country teams were also put on standby to ensure seamless customs clearance when the goods were ready to ship.</p>	 <p>Ethics approval was given, and TecEx Medical immediately set the shipping process in motion. Within 48 hours, TecEx Medical got the clinical trial commodities to the site in Canada.</p> <p>Our project management skills ensured alignment across the entire supply chain.</p>

Overall, the TecEx Medical team supports the essential agenda of biopharmaceutical companies in meeting the site initiation dates.

Our knowledge of global import compliance requirements is unrivaled, ensuring the first-time clearance of your goods.

TecEx Medical has the knowledge to provide risk-free import and customs compliance solutions to Contract Manufacturing Organizations, Contract Research Organizations, Sponsors, and Vendors in the clinical trial space.

Key Takeaways

1. The TecEx Medical team is accustomed to working within restrictive timelines. Partnering with an expert IOR ensures we can utilize our expertise in customs compliance to expedite the process and meet SIV dates.
2. Our project management skills are unparalleled. TecEx Medical has fully streamlined the process, so the earlier we can begin pre-compliance on shipments, the faster we can get approval to ship.