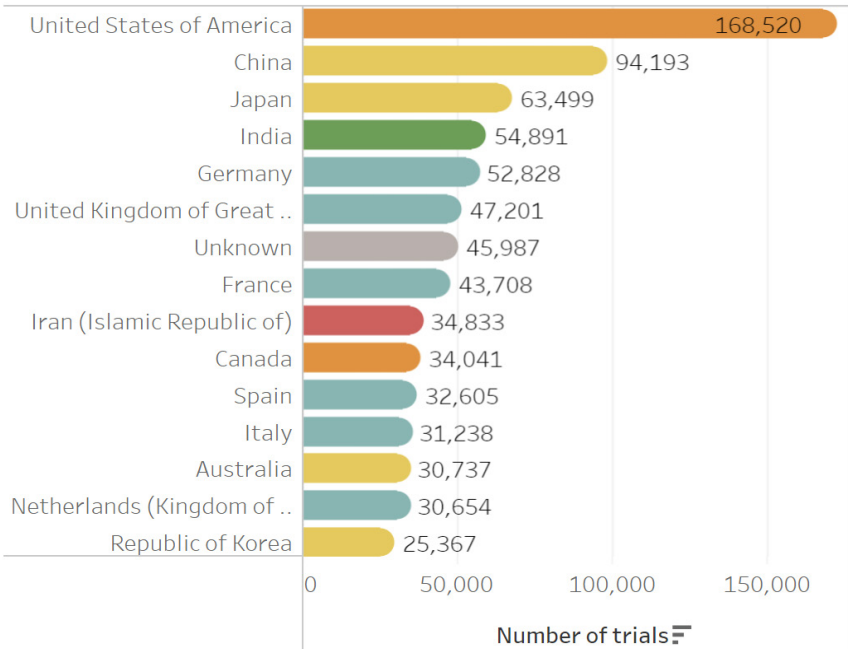
Ask RxSource | Clinical Trial Returns from Canadian Sites

RX SOURCE Clinical Services

Canada continues to punch above its weight in terms of being an attractive destination for clinical trials. While more trials are registered in the US than in any other country, Canada supports approximately 20% of the number of trial registered in the US, despite having a smaller population (about 10% of US) and a fraction of the number of indigenous clinical stage biopharma companies compared with their neighbour.



Source: https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-trial-registrations-by-year-location-disease-and-phase-of-development

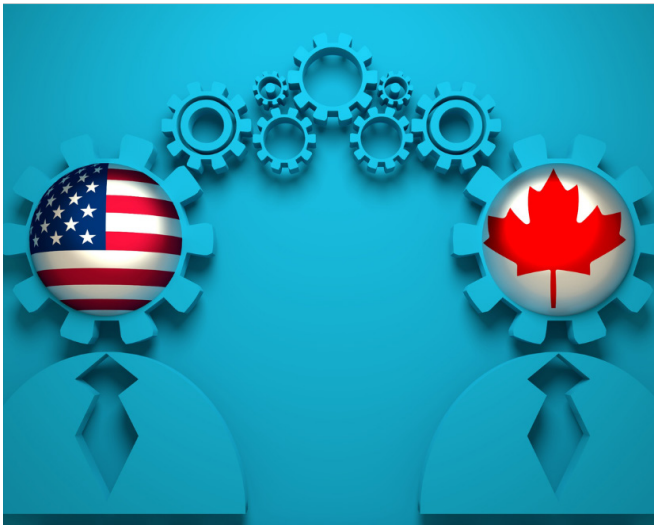
So why is this? Canada is globally recognized for the quality and expertise of its research clinicians. The Canadian research environment operates at standards equivalent to those in the US. Like the US, Canada offers a diverse population, so important in demonstrating the safety and efficacy of new drugs in all patients. Coupled with this, lower currency values in Canada allow research to be conducted more cost effectively than equivalent work in the US.

Our experience in the clinical supply chain backs this up. It is rare for global trials not to include Canada. Even clients with plans to focus their clinical developments in the US include Canada in their clinical trial plans.

Distribution to Clinical Sites in Canada

RxSource can offer local distribution within Canada. However, many of our clients ship to Canadian sites from their US depot. While we feel our Canadian site could be advantageous for these trials (shorter distances and lower courier fees, no need to cross any borders), we acknowledge our clients' desire to keep the number of depots supporting their trial to a

minimum. Additional depots can drive higher drug overages, which can lead to increase drug waste and cost over the course of a clinical trial. Trading relationships between the US and Canada, and the ability of US exporters to act as non-resident importers into Canada, can encourage companies to retain their inventory where they expect to recruit most patients – the US. As a result, despite owning clinical trial supply facilities in both the US and Canada, we often employ only our US depot in support of clinical trials, especially those with only a small number of clinical sites and patients in Canada.



Clinical trial returns from Canada

What happens to unused or returned medication at the end of a clinical trial? Regulators demand that all drug produced for clinical trials, shipped to clinical sites and supplied to patients is accounted for and ultimately any leftover medication undergoes certified destruction. While certified destruction can be performed locally, and arranged by the clinical sites themselves, Sponsors are ultimately accountable for the final disposition of medication so prefer to do this centrally themselves.

Since many Sponsors distribute drugs for North American trials from a central depot, usually located in the US, this depot provider also provides a central location for returns from clinical sites. This is a straightforward process for returns from US sites. What about returns from Canadian sites? Sponsors often tell us this process can be complex and expensive.

- Shipping medication, which is after all of limited value, from Canada to a returns site in the US can be costly.
- As drug is being re-imported into the US, each import may be subject to Importer-of-Record (IOR) fees from the vendor.
- Requirements for accurate paperwork from the site, and close liaison between the site and courier to arrange cross border transportation, drives some vendors to insist on the use of premium couriers for this activity. Preparing paperwork for returns destined for export can also create a greater burden for clinical site staff. A high price to pay for medication destined for the incinerator!

All of which adds cost and complexity to the trial, without adding any real value.

Our Canadian facility offers a full returns service to our Sponsors and their clinical sites. We also offer this as a standalone service to Sponsors who are using other vendors for their outbound distribution. Based on our experience this can greatly simplify, and reduce the cost of, this often overlooked but critically import part of the clinical trial supply chain for Sponsors. From a clinical site perspective, the ability to send returns to a domestic facility allows them to

ship unused medication on a more regular basis, rather than waiting until the end of the trial, freeing up much needed space in their own pharmacies.

If this is an area where you are struggling, we are happy to help! Contact us on solutions@rxsource.com, and we will be delighted to work with you to implement a solution that works for you and your clinical sites.

Contact us

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