

FAQs

How US Clinical Trial Sponsors Can Establish Effective VAT (and Other Related Tax) Models to Address International Clinical Trial Costs

Q: What is VAT?

A: VAT (Value Added Tax) is a sales tax. It is chargeable by businesses if they are making “taxable supplies” (i.e. sales of goods or services subject to VAT) purchases and/or payments above a certain threshold. But unlike US sales tax, VAT is paid by all parties in a chain of transactions, with the VAT charged by the supplier normally being recovered by the recipient. The difference between the VAT paid on purchases, and the subsequent VAT charged on sales (the “value added” part), is payable to the appropriate national tax authorities.

Q: On what goods and services, and what rate, is VAT determined?

A: Unless specifically exempt or zero rated, most goods and services are liable to VAT assessments. How much VAT is assessed and collected is determined by each individual country. Most countries have multiple levels of VAT assessment depending upon the nature of the goods and services sold. The rates range from a low of 5% in Japan to 25% in Denmark. In the EU the standard rate of VAT is usually between 15% and 25%, with a second “lower rate” of between 5% and 9% on a country-by-country basis.

Q: Against what type of expenses and costs is VAT incurred?

A: Typical examples of expense and spending categories, related to clinical trial activities, against which VAT is normally incurred at the standard rate include:

- a) Research fees provided by or to commercial organizations
- b) Outsourced laboratory services
- c) Media and advertising costs
- d) Other professional and advisory fees
- e) Lease payments or the purchase of equipment
- f) Hotel accommodations
- g) Most administrative and overhead expenditures

Most importantly, any type of VAT cost incurred should be supported by a VAT invoice which clearly describes the nature of the supply and/or service and the VAT charged (or the basis for not charging VAT where appropriate). This would include:

- payments by the Sponsor directly to the CRO against presented invoices for their services;
- payments by the Sponsor directly to the PI and/or institution against presented invoices for services rendered under the terms and conditions of the clinical trial agreement;
- payments made to arms-length third parties either by the Sponsor, the CRO, the PI or the institutions (i.e. out-sourced laboratory services, etc).

Q: Who must pay VAT?

A: Any purchaser of goods or services from a VAT registered business.

Q: Can a US clinical trial sponsor recover VAT payments made during clinical trials?

A: This depends upon the tax laws and regulations in each country. But generally a US Sponsor that is not established (incorporated) in the country where the VAT is charged is entitled to make a claim for VAT recovery that it incurs in going about its business, provided it is VAT on goods or services purchased **directly** by the Sponsor. The claim is normally made directly to the tax authorities and there are different criteria that apply in the various countries that need to be complied with, and strict time limits that need to be met in order for the claim to be approved for payment.

Q: How can a US clinical trial sponsor minimize its exposure to VAT?

A: Payments for supplies and services, by US Sponsors in (or to) overseas countries are generally not liable to VAT. It is therefore vital to ensure that all organizations supporting the clinical trial are registered for VAT in the country where VAT costs are being incurred. The US sponsor, the CRO retained by the sponsor to conduct, administer and oversee the clinical trial activities, and the institution involved in patient recruitment, dosage, testing, etc. must all be considered in the creation of a coordinated VAT and tax strategy. This process should ensure VAT reclamation is maximized in the country where it is incurred.

Q. What are the key elements for US clinical trial sponsors to establish an effective VAT auditing, documentation and minimization structure?

A: Exposure to VAT (and similar GST type taxes) related to clinical trials can be minimized if the Sponsor mandates every third party and arms-length vendor, involved in the trial and providing any overseas services or supplies whatsoever, undergo a detailed VAT audit and takes the required actions before the trial begins. This will include the proper formatting and organizing of invoices, using correct accounting and ledger terminology when describing the services or supplies being provided, filing the required forms to make the proper registrations and submitting returns to recover the VAT, etc. However, if these action steps are not organized or tracked in a formal manner, the US clinical trial sponsor can be required to pay unnecessary taxes in the form of higher service fees to cover the VAT that is not recovered. If this is the case, the recovery of tens or hundreds of thousands of dollars throughout the course of an entire clinical trial could far exceed the cost of establishing a detailed, well organized VAT and related tax structure.

Q: Can a US clinical trial sponsor recover VAT incurred before a VAT registration is made?

A: Yes. Some countries will allow previously paid VATs to be recovered before the VAT registration is obtained. Each country will have different rules governing this process. For example, in the UK there is a time window of recoverable VAT payments made up to six (6) months prior to the registration date. However, the mechanism for recovering this VAT will only be available to the CRO, the PI, the clinical site and/or third party vendors after they receive their VAT registration.

Q: Who is Blick Rothenberg? What are their credentials in helping US life science companies set up an effective VAT treatment and tracking structure?

A: Headquartered in London, Blick Rothenberg is a leading UK firm of Chartered Accountants. Our firm is a full-service chartered accountancy practice of 20 partners and 170 additional support staff. Founded in 1945, BR not only provides VAT and related tax advice but also offers a full portfolio of accounting, audit, financial and other related professional services to multinational companies with operations on a global basis. For further details please see the firm's profile under the "Resources" tab at www.ClinicalVRS.com.