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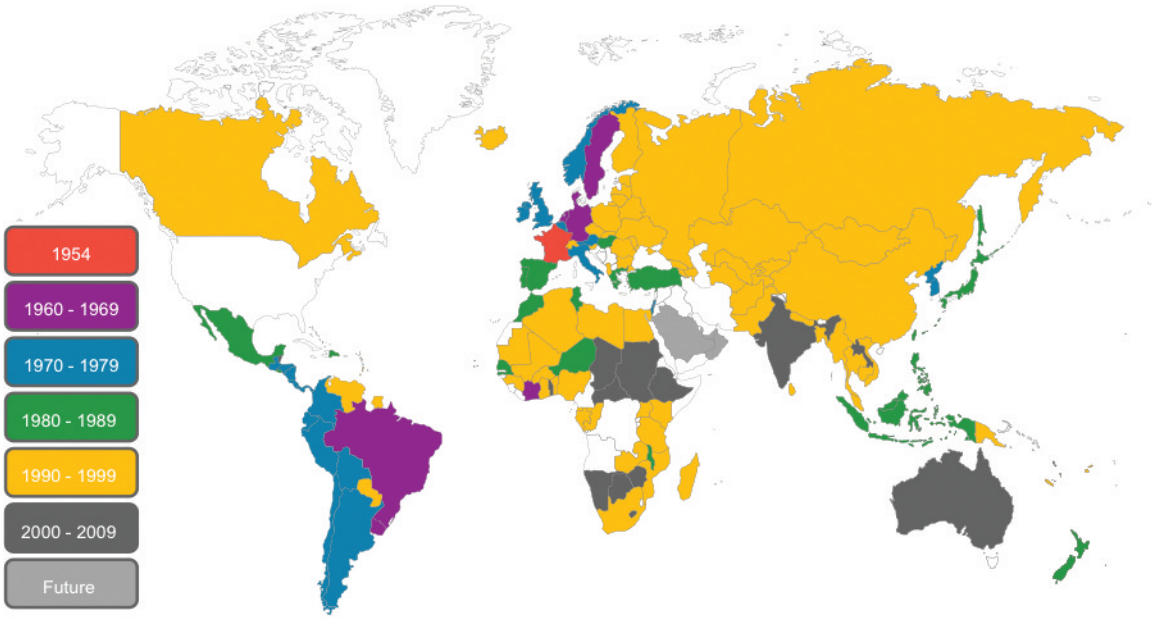
4 Tips for Mitigating VAT Exposure

As clinical trials become more global, sponsors and CROs face a myriad of financial, contracting and compliance challenges. One of the most pressing: understanding and managing the impact of Value Added Tax (VAT).

Ranging from 5 to 27 percent, VAT can instantly add to the grant spend budget if the appropriate planning is not done. Adding to the complexity is the fact that rates and rules can vary from country to country. For instance, Japan has one of the lowest rates at 8% (rising to 10% in October 2015) while Hungary has the highest individual rate at 27 percent.

Below is a graphical representation of the global spread of VAT implimentation over the past 50 years.



The good news is, depending on the tax laws of the countries in question, sponsors and CROs have opportunities to minimize or recoup some of the VAT exposure.

When Sponsors and any chosen payment providers are aware of the global implications of VAT to a Clinical Trial, planning excersises can be undertaken at an early stage. VAT does not have to be a complex and time consuming element when decision makers, and systems and processes are prepared effectively. The following page contains the main considerations when looking at the VAT impact on a study.

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The key areas to focus on are:

Be diligent about documentation.
Trial documentation should always follow a clear audit trail for payments. CTAs should be reviewed in accordance with the local VAT legislation of each country. Agreements should cover these key questions:

- To whom are the services actually being provided?
- What is the VAT treatment of those services?
- How are the invoices being raised and do they meet certain requirements?
- Who is making the actual payments?

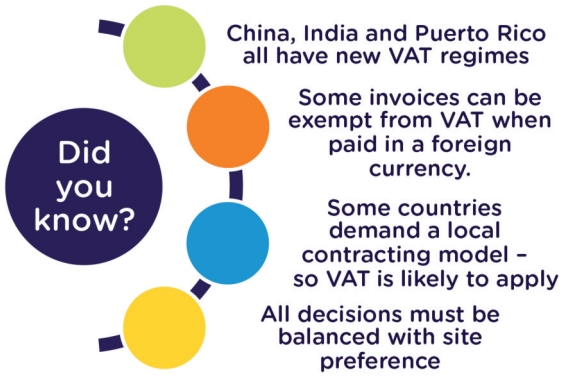
Maintain visibility.
Any VAT amounts on invoices should be traceable and a clear, separate component of a grant budget. This will provide the basis to follow up on available VAT credits with local authorities, and ensure that the credit is ultimately refunded correctly where applicable.

Invoice properly.
Each country has its own VAT rules and invoicing requirements. As legal documents, invoices should meet local legal requirements.

Mind the cash flow.
Any VAT due must be paid before it can be refunded. Depending on the country in which the reclaim is processed, the refund may take some time to come back to the claimant. Thus, it is critical to factor in cash flow considerations to any grant spend.

Other considerations?

There are particular nuances to some of the global tax regimes that may allow exemptions, or force a certain contracting model. To make sure a Clinical Trial is managing costs effectively, detailed advice on the countries involved should be sought. For example:



Careful planning will enable a Sponsor to avoid the most common VAT pitfalls, but new regimes and regulations are appearing all the time. However in all cases, a site's opinions should be considered. For example in cases where VAT can be mititgated by paying the site in a foreign currency, there may be resistance from sites who would find this cumbersome to their internal processes.

About DrugDev

DrugDev is an innovative technology company which provides cloud-based solutions to help sponsors, CROs and investigators do more clinical trials together. Built around the largest global network of active opted-in investigators, DrugDev's unified solutions suite optimizes site selection and startup, investigator payments and clinical operations. DrugDev also serves as the trusted third-party host of the revolutionary Investigator Databank collaboration and powers the TransCelerate Investigator Registry. Learn why 9 of the top 10 sponsors and 4 of the top 5 CROs rely on DrugDev technology to do more trials at drugdev.com.