



Power of Partnership

ISSUE 04

POP is devoted to providing transparent and collaborative
clinical trial financial management news

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POP VOICE

My journey as a patient

by T.J. Sharpe

How does a technology company paying sites really affect trial participants? Turns out, enabling this vital transaction is essential to giving patients the chance to find the right treatment for them. As a newly-diagnosed stage IV melanoma patient, I learned - quickly - that clinical research is a business, and like all businesses, there are some hurdles that present themselves as part of conducting groundbreaking, life-saving, health-altering “business”.

When I entered the hospital for the first time, not only did I have stage IV melanoma, I also had a two year old daughter and 4-week-old son. My diagnosis, in 2010, came with a median 18 month expected lifespan; 9 out of 10 people treated with standard-of-care chemotherapy at that time would not survive five years. I had a 50/50 chance to make it to Tommy’s second birthday; it would take a small miracle to see both kids start first grade. I needed treatment, but was only presented with status quo medicine and its dismal prognosis.

Looking for that miracle, I came across a clinical trial that, theoretically, showed a lot of promise - a T cell therapy that was personalized, alongside a new immunotherapy. I would be the first person to ever try the two treatments sequenced together, a daunting but opportunistic set of circumstances that was far more appealing than a two-years-left roll of the dice. It was hope when there was little else. I was ready to go, figuratively and literally, as we uprooted our family and temporarily moved four hours away to the trial site.

However, even though things were generally in place for the trial to begin, the contract between site and sponsor was still being finalized. It didn't matter that my tumors continued to grow waiting for finalization, or that the clock was ticking on my 24 months. The trial couldn't start without the John Hancocks of five lawyers who had no knowledge of little Josie and Tommy, nor a vested interest in getting their Dad a life-saving treatment stat.

Fortunately, after a little (OK, a lot) of wrangling with a few legal departments, the contract was completed and the trial began. That treatment ended up not working, but a second immunotherapy trial did, and I became one of the first complete responders to what is now Merck's blockbuster Keytruda. After five years, two trials, and four different drugs, I was cancer-free.

My example may be contract-related, but anyone with industry experience knows that the budget negotiation is the precursor to getting a contract signed, and site payment is the end result of these transactional processes. Timely site payments enable continuity of research; they also ensure that sites remain viable and continue to support clinical research as part of their treatment and business plans.

Clinical trials are an essential part of a late-stage cancer journey; not only do we need them to bring new therapies to the broader patient population, they are sometimes the last, only, or best hope a patient has to combat a serious or terminal diagnosis. And trials cannot happen without the unsexy but essential operational steps to ensure the sites, doctors, nurses, and other healthcare professionals get the compensation they need to execute a trial.

If you are ever unsure if your job is patient-centric, or find yourself wondering, "Is what I am doing really making a difference?", remember the not-so-little-anymore kids whose Daddy gets to work at Medidata, and all the moments in the 10+ years they and I have been gifted, all because a team of people made executing clinical research a possibility. Thank you for that gift.



Ten years to the day apart (first photo was the day before my surgery)



"We are here to add what we can to life, not to get what we can from life."

– William Osler



POP PERSONALITY

VIVEK TALWAR

I am Vivek Talwar. I am the product lead for our Rave Site Payments solution. I consider myself a curious person, which is how I ended up working in product development. Medidata is my first job in the life sciences domain and it is something I am really enjoying. Prior to my current role, I spent a few years working in the telecoms and European travel industries. Working with site payments continues to be a challenging yet rewarding experience, especially with the amazing team that I work with. Outside of work, I am a bit of a gastronome, although I don't cook much. I am more of a food critic. When I am visiting a new town or city, my to-do list starts with researching popular places to eat. My two little girls keep me busy, but whenever I have free time I spend it on light DIY projects around the house or watching football, a film, or a TV series. Working at Medidata with the site payments team is such a pleasant experience. I am excited for the innovative things we have planned for the product.

We asked Vivek to answer a round of "Would you rather" questions, and here's what he said:

Would you rather...

be able to talk with animals or with plants?

Plants- maybe then I can know what I need to do to take better care of them.

live without internet or air conditioning?

Without air conditioning as we only get 2/3 days of hot weather in England.

live in a cold or warm climate?

Warm climate. My answer would have been different 15 years back but now that I live in the UK in cold weather I know better.

spend the night camping or at a luxury hotel?

At a luxury hotel. With little kids I think my camping days are now behind me.

lose your car keys or smartphone?

Car keys.

be a child your entire life or an adult?

Child. It's way more fun even though it involves being told what to do a lot of the time.



IMPACT REPORT

How to manage global tax

by Holly Leslie

What is global tax?

Global tax is taxation at a country-by-country level, often referred to as indirect or transactional tax. Examples are VAT (value added tax) and GST/QST. There are upwards of 170 countries globally that have VAT regimes—the US is one of the few that does not. These taxes range from 4.5–27%. There are some jurisdictions where payors may need to ensure taxes are withheld from payments, as well. Russia is just one example. If withholding taxes apply, these funds should be offset from the payment and immediately remitted to the corresponding tax authority as there are filing time restrictions and penalties when not paid in a timely fashion. There are several considerations when handling global tax.

How should you handle it?

Ultimately, your goal is to be in a zero-rated VAT situation (meaning VAT would be applicable for the service performed but is exempt). The general rule of thumb is if the site/payee and the service recipient (usually sponsor but if the CRO is contracting on their own paper, it *may* be them) are in the same country, VAT will apply.

Except for Australia, this is rarely a legal requirement but the way it's simply “always been done” for a host of reasons such as language or business custom, this results in added tax cost that may simply not be recoverable as well as an added burden for sites and internal sponsor/CRO staff for recovery tax returns.

If the site/payee is in different countries, even within the EU, it is generally considered a cross-border transaction. A regional contracting model will largely ensure that VAT is zero rated. Have the tough conversations with local entities—consult tax and legal professionals when in doubt. If you can't avoid it, make sure you are prepared to recover it. Advanced preparation is key!

Make sure that invoices are formatted correctly. Universal invoice formatting requirements include:

- Clearly identify the date (and this date must pre-date the funds being paid)
- The payee's unique invoice number (from their accounting system)
- Clearly identify the payee, its VAT registration number and address (this may be contained within the letterhead)
- Clearly identify the name of the "service recipient" as defined in the CTA
- The math must add up correctly - on the invoice and the value of the payment transmitted (wire and banking fees are normal post transmission deductions)
- Additional fields may be required depending on jurisdiction

Know how to file VAT recovery returns in each jurisdiction *before* you begin contracting within it. Some jurisdictions require e-submission, and some require paper. Being submission ready isn't just an FDA thing—decentralized processes will make VAT returns difficult, so across the portfolio reporting is a necessity!

Not all countries will require proof of a transaction with filing, but if there is a query or audit you will be required to provide additional documentation so having a central repository for invoices is essential—if you can't answer the query, you will not recover the funds (even if you can answer the query, you still may not as FYI). VAT returns are never a guarantee. The only safe strategy is one that avoids paying VAT.



What should you be concerned about?

Balancing risk vs. reward in geographies that offer research tax credits (ex. Canada)

- Many times, to be eligible for these credits, the company and payee must be locally contracted and appropriately registered with the local tax authority. However, what is the ROI on credits vs not having to pay local tax at all? Do the analysis (and in truth, this analysis should be reviewed regularly as volumes and tax credit laws change).

Recovery or lack thereof—this can represent more than 20% of a protocol's expense that you may simply not get back. Many organizations consider VAT a sunk cost.

- Take a hard look at what you have paid out in VAT over the last 2-3 years—how else these funds could be invested to support other corporate objectives?
- Even if you did recover it, what was the cost of that recovery? Staff time, site time, the future value of the funds, etc. You could be reinvesting that money into your pipeline.

Paying avoidable or incorrect tax

- Anecdotally, when one of our customers enabled auto tax in Canada they identified that a site had been using a significantly higher tax rate than they should have been...for several years. An innocent mistake on the site's part, completely avoidable on the sponsors!
- Remember, even if VAT is recoverable, it can't be recovered until it's paid. The funds will be out of pocket until when they can be recovered which can be months or even years—sometimes even after a trial is finished. Be sure to incorporate VAT into your planned budget.
- Sites generally do not have tax professionals on staff, however, Sponsors and CROs do. Historically the burden to calculate taxes has been shifted to the site with zero support from the industry. Solutions like Rave Site Payments bridge this gap in a reliable way with automated & independently validated tax logic.

When should you leverage experts?

Whenever you are entering a new country or region, do the due diligence to avoid costly mistakes. If you are routinely carrying taxes in your protocol budgets, get an expert opinion on whether your contracting model is as efficient as it can be. Recognize the experts in your vendor network are great sources for guidance—this doesn't have to be a high-dollar consultant or FTE.

What do you wish you knew before dealing with global tax?

That “the way it's always been done” is generally accepted as justification for not doing it differently when it comes to tax management—I have had more conversations than I wish to count with organizations insisting that they must contract locally because their team believes that is the requirement when no one has done the research to validate it or the research was done years ago. Laws change!

What can everyone start doing right now with global tax?

Evaluate your contracting model strategy first and foremost. Very few jurisdictions require locally contracted agreements by law. In fact, if local contracting is used, that may dictate whether payments can be made to cross-border payees or not so this has up and downstream implications.

Evaluate your position on sites doing all the heavy lifting—sites are in the business of treating patients, not managing tax code. We made strides in the industry with the general acceptance of a pro forma so why not automate the tax as well?

HAVE YOU HEARD

RAVE GRANTS MANAGER

Enhanced Country-specific Ratios

Rave Grants Manager has made enhancements to country ratios. Country ratios are a set of measures to evaluate a country's economic and social status. This enhancement ensures users have accurate and reliable comparisons to determine the fair market value (FMV).

Derived Specific Configuration

Rave Grants Manager has made enhancements to derived costs. Rave Grants Manager Planning (GMP) is not only allowing users to select the preferred types of benchmarking, but with the recent 123% increase of available AMA CPT codes, combined with the updates to derived costs, users can now confidently build budgets with no data gaps.

Column Header Update

Rave Grants Manager has updated column header from "Medium" to "Median" to reflect the quantitative FMV accurately.

Pendo Tool for Rave Grants Manager Contracting

With the addition of Pendo, users have a better product experience, interactive and efficient customer support, and product analytics outputs that ensure usage and needs are assessed when confirming feature implementation.



RAVE SITE PAYMENTS

Company Code Management

Rave Site Payments has added a company code to organization setup. This enables consistency and eliminates errors with payee setup.

Enhancements to Manage Payments Data by Country

Rave Site Payments now has the capability to filter views for costs and payments by country. This helps users view data in the payments application based on country and membership, powering faster processing cycles.

Payee Pick List Enhancement

Rave Site Payments has introduced a way for users to easily identify and select payees, speeding up the site setup process.

Holdback Filters

Rave Site Payments has enhanced filtering results to include holdback payments to allow the user to quickly locate relevant holdbacks for processing.

Multiple Tax Rates w/ Overriding Feature

Rave Site Payments now has the ability to override tax rates at the cost line item level, giving the user the flexibility to have more than one tax rate for one invoice.

Proposed Tax in Site Initiated Invoice Workflow

Addition of a 'suggested rate' in the Site initiated invoice workflow to advise sites on the rate per Medidata tax engine.

Remittance to Payee

Adding an internal pathway for the generation, storage, and sending of remittance details provides the payee with payment details that support ongoing payment reconciliation efforts.

Site Payee Contract Approval Workflow

Rave Site Payments is introducing an approval workflow during the site setup process for the Site Payee Contract. This enables better compliance and control over the budget/contract setup process.

For more product information, visit the knowledge space

[Rave Site Payments Knowledge Space](#)

[Rave Grants Manager Knowledge Space](#)

GROW WITH US

WEBINARS & VIDEOS

[Rave Clinical Trial Financial Management Product Video](#) * NEW

[Innovative Clinical Finance Video Series](#)

[Medidata Elevating the Site Voice](#)

[The Future of Site Budgeting & Payments: Turning Lessons Learned Into Solutions](#)

[SCRS Power of Partnership Webinar: Raising the Site Voice: The Future of Clinical Research Depends On It](#)

PUBLICATIONS

[Clinical Trial Financial Management Content Resource Page](#)

*NEW (Find all POP issues here)

[How Sponsors and Sites Can Achieve a Harmonious and Optimized Site Budget Negotiation Process White Paper](#)

[Translating Your Protocol into Clinical Financial Management](#)

[Clinical Trials Arena Article: How a well-planned clinical trial budget can help prevent burning bridges](#)

BLOGS

[Financial Effects of Site and Patient Burden](#)

[Site Dissatisfaction and Challenges in Clinical Trial Financial Management](#)

[Clinical Trial Financial Management: Investigator Grants Clinical Trial Forecasting](#)

[NIHR & Medidata: Working Towards a Global Clinical Trial Budgeting Approach](#)

[NIHR & Medidata: Knowledge, Expertise & Collaboration Lead to Improved Clinical Trial Budgeting](#)

CASE STUDIES

[Medidata's Full-Service Site Payment Solution: Mid-sized Sponsor Manages Study Finances across Hundreds of Sites](#)

[Regenerative Medicine Pioneer Issues Site Payments Accurately, on Time, and Transparently](#)

PODCASTS

[Collaborating for Transparency: Site Budgets & Payments](#)

EVENTS

NEXT Boston-, April 25 - Register [here](#)

Bio-IT World Conference & Expo, May 16-18- Register [here](#)

SCRS West Summit, June 7-8- Register [here](#)

ASCO Annual Meeting, June 2-6- Register [here](#)

More NEXT City Events dates coming soon!

