MEDIDATA

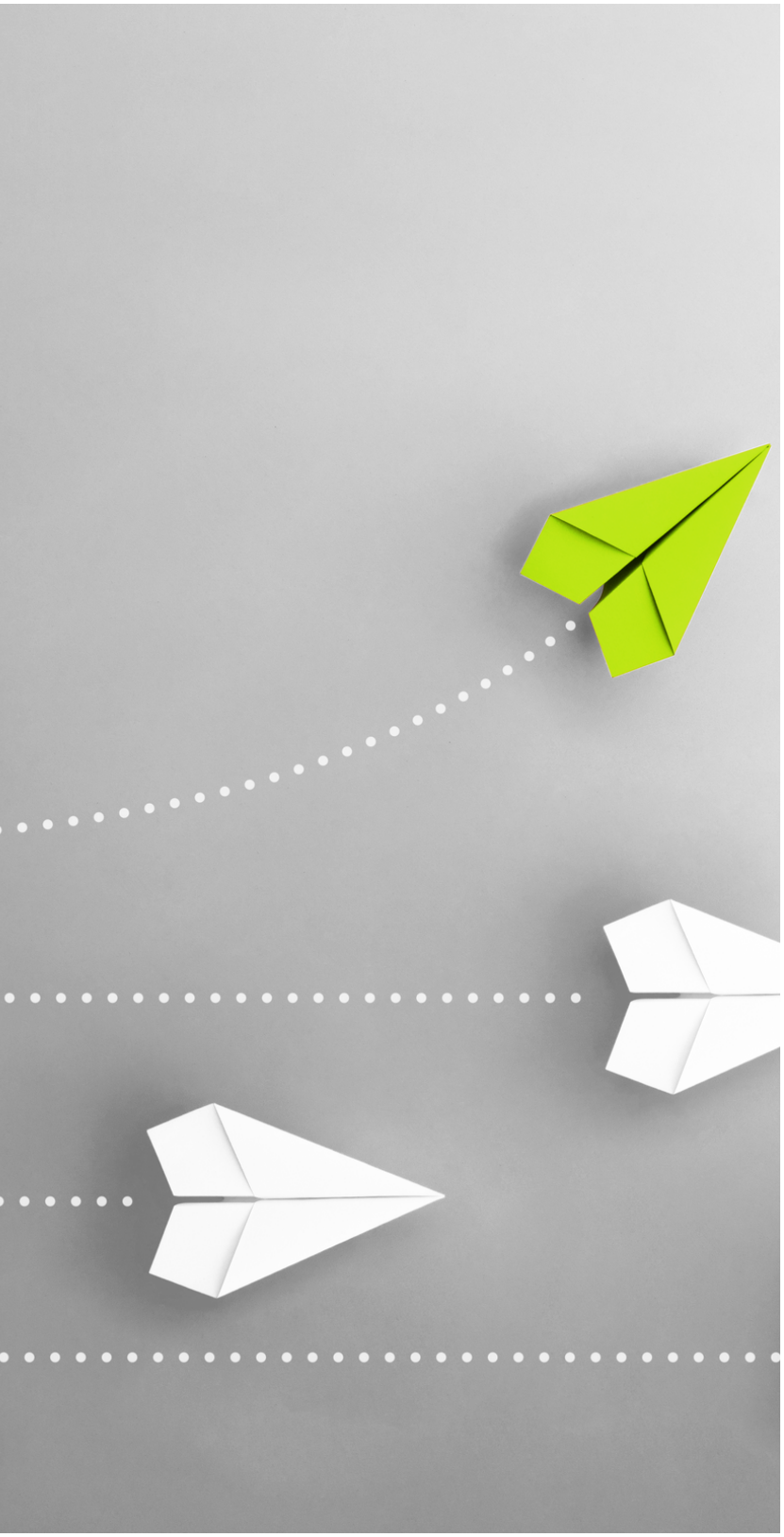
POP

Power of Partnership

ISSUE 03

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

POP ISSUE 03 CONTENTS



POP VOICE

Where's my payment?

by Melanie Fuller

Working in site payments for a large CRO, one of the most common complaints I received from sites was, "Where is my payment?". If we look at the process of making site payments on a global scale, it's easy to see why payment delays are common. For example, invoices must be created, requested, chased, received, assigned, processed, verified, approved, and funded before they are disbursed to the sites. And these steps don't factor in varying tax implications and country-specific financial compliance requirements. Each process step relies exclusively on the previous one being completed by designated individuals immediately. Sponsors and CROs need help with the approval process, which oftentimes requires the involvement of multiple departments to initiate even a single urgent payment to a site.

At any point within the process, a site may be passed from pillar to post to gain visibility into their accounts receivables. Even after payments are received, sites can struggle to reconcile received amounts against applicable study costs. I often found that in urgent cases, sites could produce a requested invoice for payment within hours, but the Sponsor/CRO workflows mean they may not receive that payment until weeks or even months later. Stringent invoicing requirements also mean that invoices submitted could be rejected often and repeatedly. In some cases, I saw sites eventually admit defeat and have the CRA submit the invoice on their behalf to get it over the line.

Another thing I learned quickly during my time at a CRO, was that accurate and timely payment equated to happy sites. Happy sites are more motivated to recruit participants, complete EDC data accurately, adhere to CTA / invoicing requirements, and partake in future studies.

CONSIDERATIONS

AUTOMATION

When addressing the question, "Where is my payment?" consider reducing the time between a visit to payment and increasing a site's access/visibility into their payments. Leveraging automation and pinpointing cross-department bottlenecks can significantly help speed up the process end to end, but what is just as important is giving sites that feeling of governance over their payments. Real-time visibility into payment status can help reduce operational effort on the Sponsors' part in fielding / investigating queries while providing sites with that much-needed oversight and assurance of reimbursement.

Considering this, let's examine a couple of examples of how Medidata's Rave Site Payments helps reduce the time between the visit to payment and increase payment visibility for sites.

SELF-SERVICE INVOICING

Rave Site Payments includes a site portal, which allows sites and their designated employees to create and submit compliant invoices with a click of a button. Instead of generating invoices, sites can review costs in detail, reflecting work completed with the bonus of having any corresponding tax applied by default. With this, clinical staff needn't worry about having to 'double' as accountants and can focus their time solely on the clinical needs of the study.

With the site portal, the potential for reducing payment processing time is significant compared to existing processes involving centralized repository posting, fielding, and verifying across multiple departments. The ability to create compliant invoices automatically can be a welcome feature for those smaller institutions that may not have the means, or staff, to produce invoices manually. Thus, reducing time and burden for all stakeholders.

"We need something online, an electronic system that we can actually log into, generate payments that way, see what work has been done, what we've been paid for previously, what we've got outstanding, and generate invoices. At the end of the day, I'm a nurse, not an accountant, and I don't really want a lot of financial tasks. A lot of admin takes me away from recruiting, enrolling, and seeing patients"

Kate O'Brien, Primary Care East Midlands South Yorkshire Research Network

VISIBILITY & RECONCILIATION

During my time working with site payments, I recall receiving many frustrated emails from principal investigators about how insight into their payments felt like a mystery. This annoyance is understandable considering how sites need to plan labor costs & staffing, lab set-up, pharmacy stock, patient meals and travel compensation, and the list goes on! In most cases, sites felt reassured when they have visibility into their payments, rather than a very quick payment, so they can plan their cash flow and reduce reconciliation efforts.

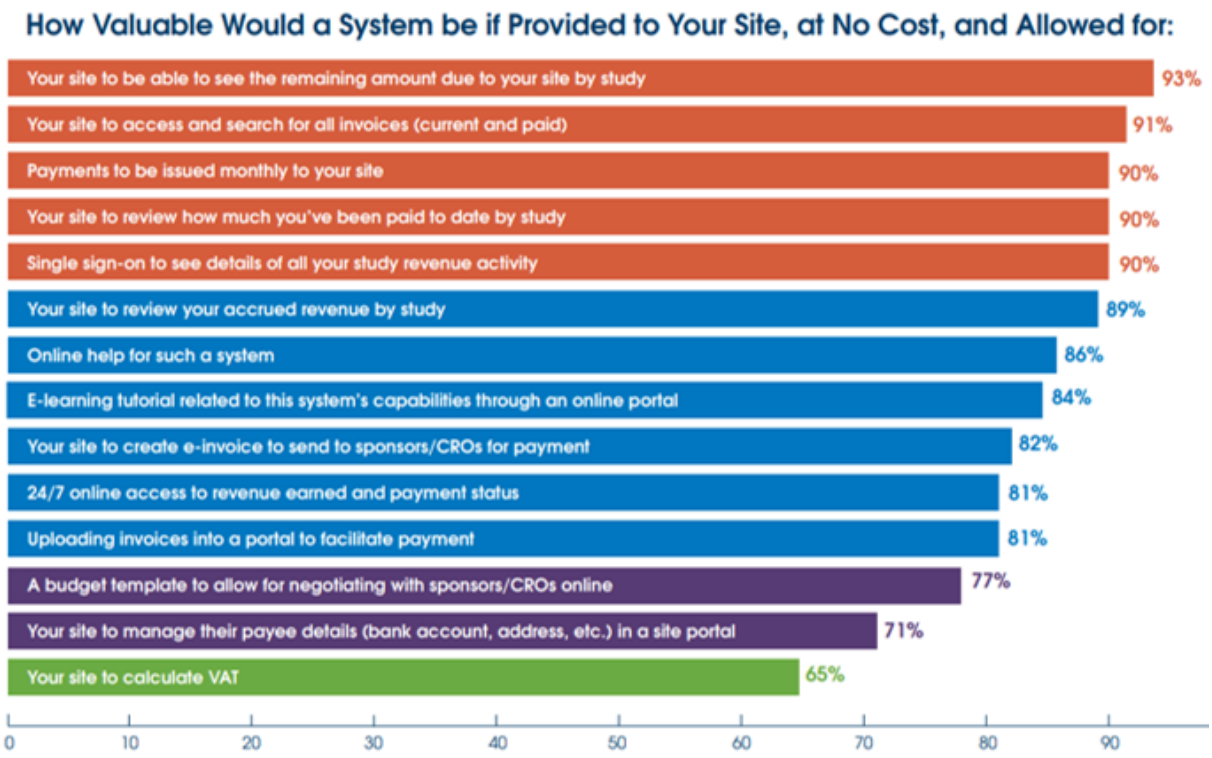
The Society for Clinical Research Sites (SCRS)'s white paper "Site Budget Development and Payment Systems: A Call for Transparency from Clinical Research Sites" highlights direct feedback from the sites that there is a huge need for technology to gain visibility of payments and invoicing.

THE SOLUTION

With payments, sites need real-time visibility and granularity. When I log onto my online banking app, I can see which payments are taken from my current account balance and those pending that are yet to clear. The Rave Site Payments site portal provides critical oversight into not only payments due imminently but also those coming next, those waiting on approval, and those rejected or held back. The dashboard within the site portal provides on-hand access to payable cost data from generation to disbursement in each stage of the payments process.

The subject-level detail can be exported and referenced against captured invoice numbers or payment reference IDs, allowing sites to know what the payment is covering and removing the mystery behind their received payments. Detailed oversight helps sites to feel more involved in the journey of their payments, more engaged in the study, and supports financial planning and reconciliation.

80% OF SITES FAVOR A SYSTEM FOR INVOICE MANAGEMENT



SCRS White Paper: Site Payments and Patient Reimbursements: A Global Perspective, Apr 2017

"We help the organization see the value, and now the business impact is there. I would just encourage folks to be change-makers. Stand up, actively fight for what you believe is right."

– Quita Highsmith on diversity and inclusion

POP PERSONALITY

HANNA HUFF

I am Hanna Huff. I recently joined the Clinical Trial Financial Management team as the senior manager of product management. I have worked with SaaS payments products in both the health care and clinical trials industries for nearly a decade, spanning 6 years at Bioclinica as director of project management, and more recently as a senior manager of implementations at VisitPay. I am incredibly grateful to be surrounded with such talented and collaborative teams that innovate and build products together to delight. It's simply energizing!

In the last few years, I have really fallen in love with powerlifting and when I am not spending time with my husband and hauling our three kids to all their hobbies, I am working diligently toward breaking my own lifting records. You might also find me misting and fussing over my indoor plants, and gardening outside when the weather permits. It's one of my sincerest joys to see all the labor I put into my garden to come to fruition, figuratively, deliciously, and literally. Gardening also feeds my other favorite activity - getting friends together for a home-cooked dinner and for some strategic board games. And when I have a rare quiet moment - nothing is as rewarding as getting lost in a really good adventure in the form of a book.

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

Would you rather...

spend the night camping or at a luxury hotel?
Camping with the family is one of my favorite things.

explore space or the ocean?
Ocean. Growing up in the Finnish archipelago, I was always swimming, snorkeling, and finding interesting things to see underwater. That has not changed as I've gotten older.

be the youngest or oldest sibling?
As the oldest, I got to pave the way for my younger siblings, and I think they had it a lot easier. That said, I would not change that lesson in grit for anything.

be a child or an adult your entire life?
I am living my best years yet, so adult.

be named after a flavor of ice cream or a pasta dish?
Ice Cream. Just call me Blizzard.

sit at the dinner table with Darth Vader or Luke Skywalker?

I think Luke would be the better host. Although, I did have Darth Vader walk me down the aisle for my wedding.

IMPACT REPORT

The art of budget development

by Tina Mincher

CLINICAL TRIAL BUDGETING CHALLENGES

Budgeting for clinical trials is challenging for several reasons. Different therapeutic areas and indications have their own unique types of trial structure and require different patient procedures. The fact that protocols are rarely the same, not having expertise in each therapeutic area can cause issues downstream when budget builders do not fully understand the needs for a specific protocol. A lack of budget expertise can lead to delays that impact costs and timelines, which ultimately impacts patients.

Before creating the budget, it's important to review the entire trial protocol and not just the schedule of assessments. This ensures a comprehensive understanding of all procedures and non-procedures involved in the trial. Knowing and understanding the main cost drivers, such as specific country regulations that could impact price and looking at fair market value to evaluate if you're paying too high or too low, are also key.

VARIANCES BETWEEN THERAPEUTIC AREAS

Similarly to country variances, therapeutic areas will also have distinct and unique differences that will impact budgeting. Looking at three different therapeutic areas - Central Nervous System, Cardiovascular and Women's Health - demonstrates the vast differences that need to be accounted for. Below, we look at the nuances of each of these therapeutic areas, identified by analyzing Medidata's unrivalled and extensive data through its Rave Grants Manager solution.

CENTRAL NERVOUS SYSTEM (CNS)

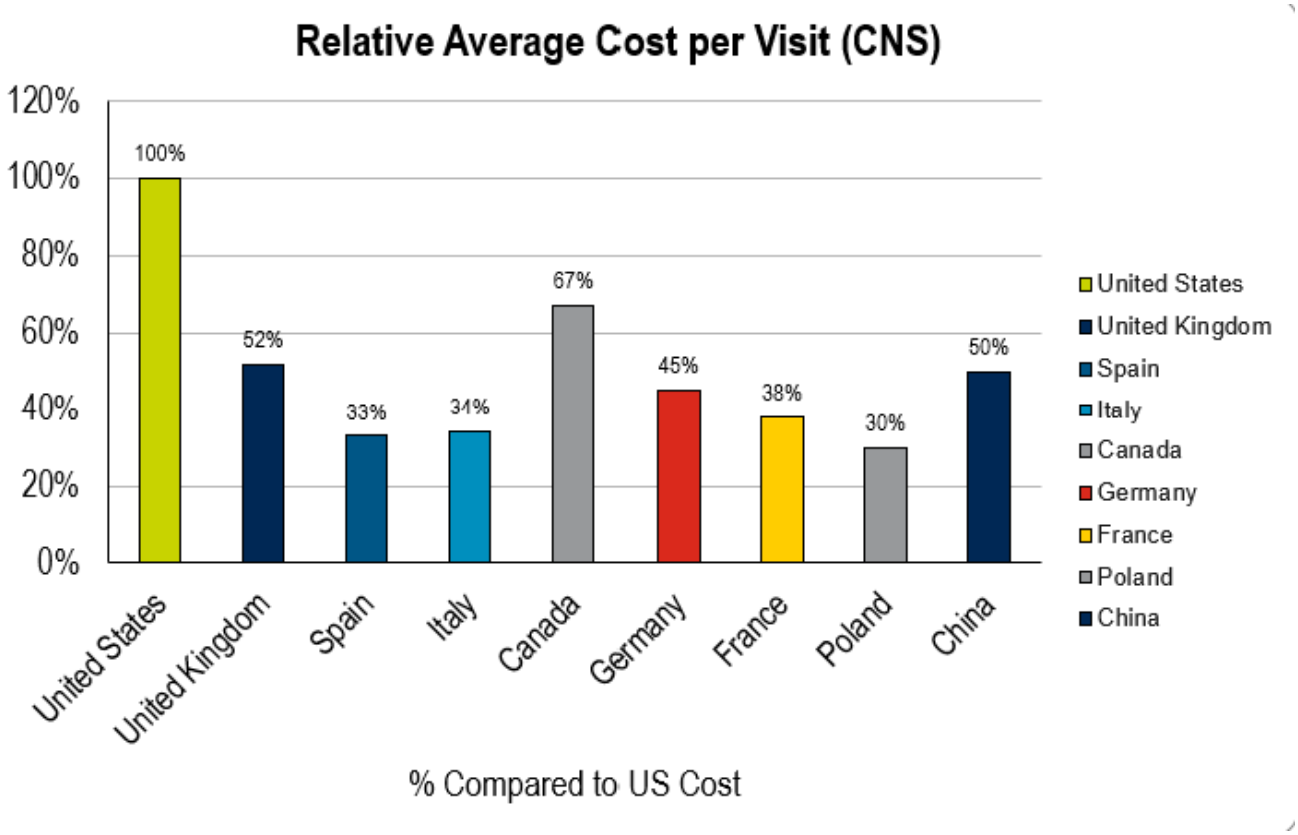


Figure 1: 2019-2021 Grants Manager PICAS Database - Average Cost Per Visit, Indication: Parkinson's Disease, Phase 3 in US Dollar.t

For the Central Nervous System (CNS) therapeutic area,budgeting for these trials can greatly differ. As shown above, the average cost per visit in a CNS trial is about half the cost in the UK and Germany compared to the US.

CNS nuances:

- It can be difficult to recruit CNS patients due to the drug washout period (the length of time that someone enrolled in a trial must not receive any treatment before receiving the trial's experimental therapy)
- These diseases are difficult to run as the failure rate for new drugs within the CNS disease area can be relatively high
- Different levels of conditions (like Parkinson's where the degree of condition varies greatly and can significantly impact staffing time) can impact staffing needs
    - There are different rating scales to determine the disease severity - and the rater needs to be trained which has to be taken into account
    - Cost Per Patient (CPP) increases, self-administered rating scales still need to be assessed by the physician
- Alzheimer's disease will include costs for caregivers (e.g. travel reimbursement for the carer)

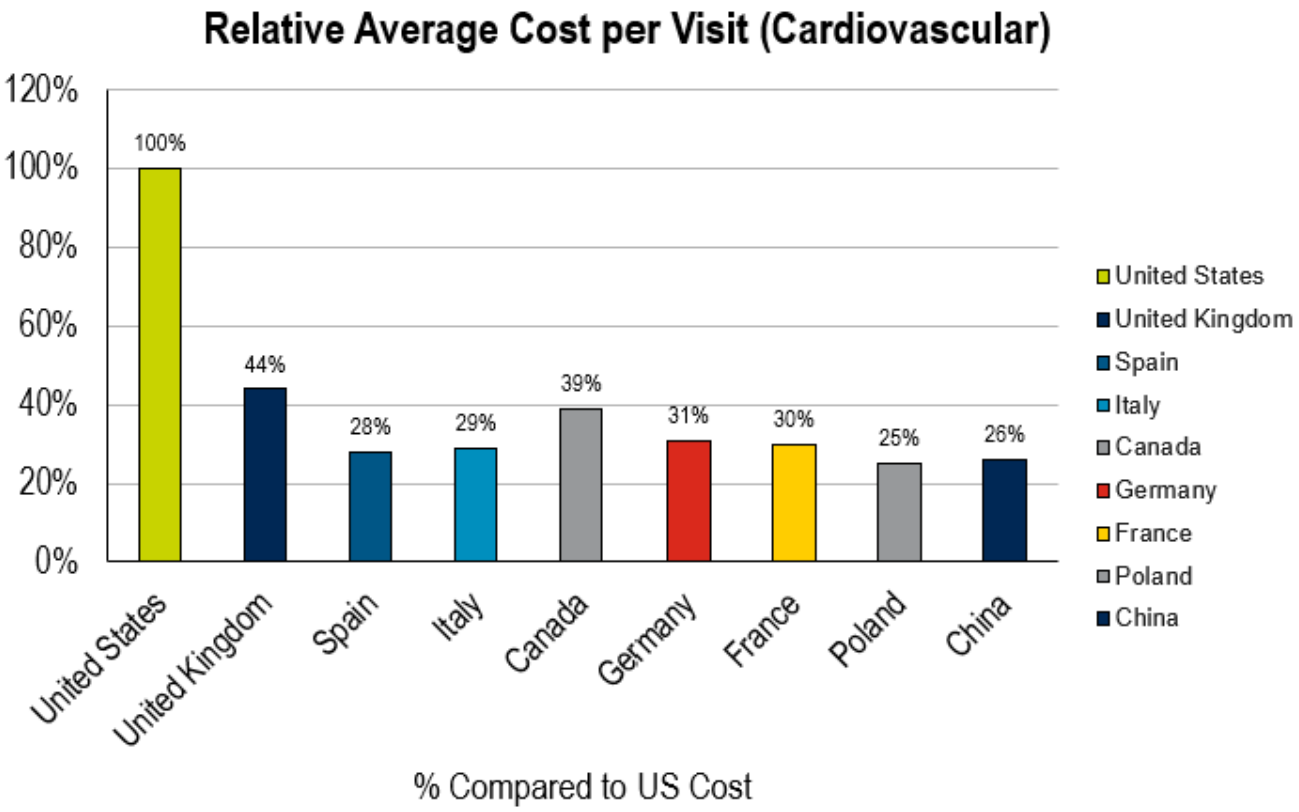


Figure 2: 2019-2021 Grants Manager PICAS Database - Average Cost Per Visit, Indication: Heart Attack, Phase 3 in US Dollar.

Budgeting for Cardiovascular studies can also have large differences as shown above, the average cost per visit in a Cardiovascular trial is about half the cost in the UK compared to the US and a fourth of the cost in Poland and China.

Cardiovascular nuances:

- There is quite a difference in costs comparing invasive vs. non-invasive indications with cardiovascular
  - Invasive indications include the need for stents and heart catheters and non-invasive includes low or high blood pressure
- Inpatient/Outpatient days (number of days staying in hospital vs. not)
  - This can massively impact study costs with overnight stays
- There will be a difference in what is covered by standard of care
  - Surgery can be a huge additional cost if not covered
- More safety labs (more regular checks and assessments)
  - For example, electrocardiogram (ECG) and echocardiogram (ECHO) tests
- Recruiting difficulties
  - For example, hard to predict when a patient will present with a heart attack – uncertain time windows and difficulty getting patient consent

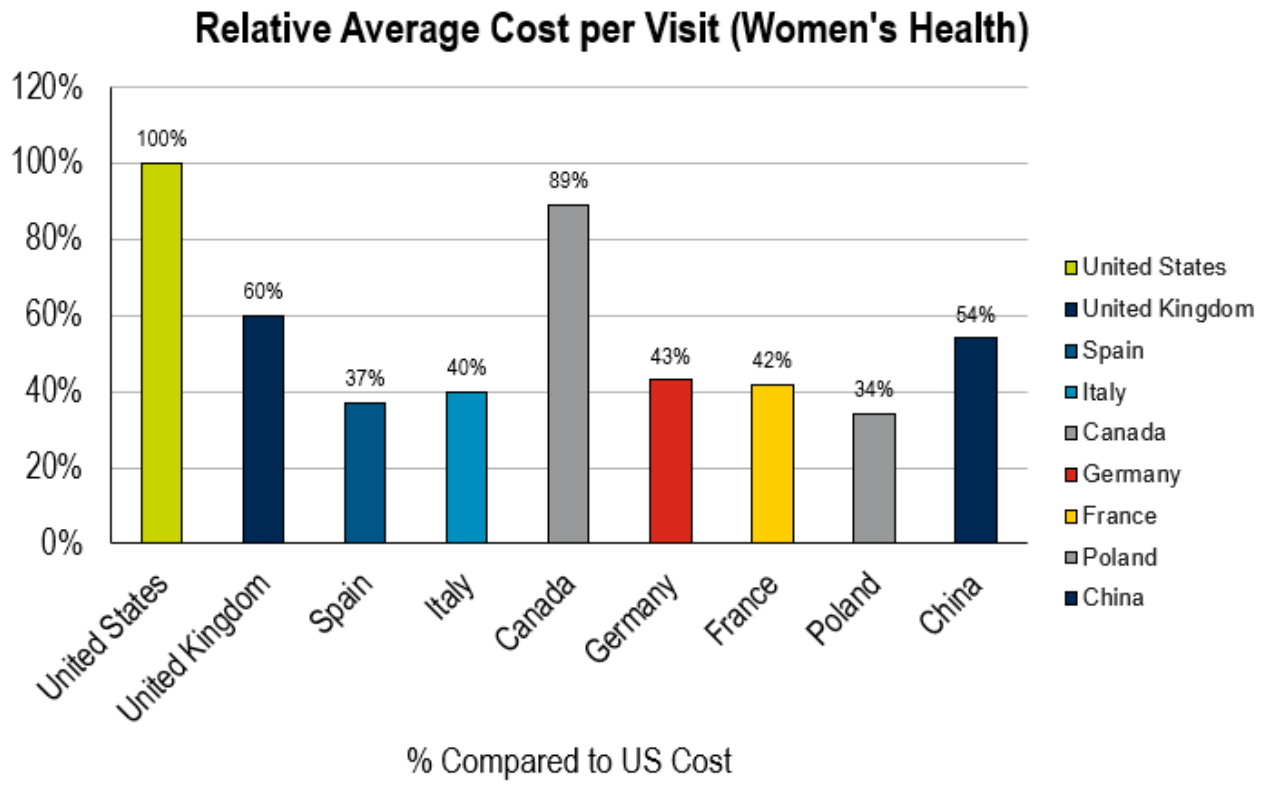


Figure 3: 2019-2021 Grants Manager PICAS Database - Average Cost Per Visit, Indication: Endometriosis, Phase 3 in US Dollar.

With Women's Health, costs for these trials can be very different. As shown above, the average cost per visit in a Women's Health trial is about half the cost in China compared to the US and about a third in Poland.

Women's Health nuances:

- Certain indications might require special procedures that can be expensive
  - For example, bone mineral density (BMD) measurements or Alkaline Hematin Method, involving chemically measuring the blood content of used sanitary products, to determine monoclonal B lymphocytosis (MBL)
- Inclusion and exclusion criteria can be very specific for gynaecology studies
  - It can be hard to recruit for studies in Endometriosis due to lack of diagnosis taking on average 10 years to receive a proper diagnosis
- Lengthy questionnaires and electronics patient diaries (about quality of life)
  - Translation, validation, compliance and collection of diary data moving from paper to electronic
- Washout period and follow up pill studies
  - Patients might be reluctant to join a study, as well as not return for follow-ups as no clear personal benefit

AN EVER-EVOLVING FUTURE

In conclusion, clinical trials are continuing to evolve with the main objective of getting new drugs and treatments to the patients that need them. Whether it's a small rare disease study with a few hundred patients or a global COVID-19 study recruiting tens of thousands of patients, one thing is certain - research teams and sponsors, and CROs need to do the appropriate research before starting a clinical trial to understand the budgeting and costing restraints, limitations and potential unseen challenges.

The expertise of Medidata and the ongoing product and client experience innovations is helping to address and mitigate these challenges and ultimately shape a truly transparent and collaborative relationship between sponsors and CROs, and sites.

Medidata is aware of the challenges and provides solutions and applications that can alleviate them. Medidata's Rave Grants Manager can help study teams build detailed and high-level forecast budgets, allowing a better understanding of the industry benchmarks. Medidata's solution incorporates data from more than 200 countries, bringing value to the investigator grant-building process in all countries, including those countries with minimal clinical trial budget experience. Medidata subject matter expert teams specialize in clinical trial financial management (CTFM). To ensure the solution's evolution and increase process awareness, the team spearheads collaborative innovation labs with CTFM client experts. These innovation labs include two tracks - budgeting and payments - which allow a synergetic environment to learn best practices and ensure that client's needs and vision lead to growth and innovation.

HAVE YOU HEARD

From 2021 to 2022, CTFM has already increased the number of yearly enhancements by > 42%

RAVE GRANTS MANAGER

Live Chat Assistant
Chat directly within Rave Grants Manager Live Customer Support and receive product alerts without having to navigate away from the application.

Progressive User Assistance
Find the help you need faster and easier than searching through online help by using PUA

Return of Country Sets
The ability to save country sets is returning! This feature will be enhanced with the new UI and also have the ability to save country sets.

AMA CPT Code Expansion
We heard you and have increased the number of available CPT codes by 123%, giving you the power to choose and build more precise budgets!

Grants Manager Knowledge Space

RAVE SITE PAYMENTS

Resource Country Membership Assignment
Gain more transparency with the ability to associate a resource to one or multiple countries.

Site Invoicing Enhancements
Site invoicing and payments data syncing have been improved! No more delays with data syncing when costs are approved to an invoice.

Reporting Enhancements
There is now an enhanced Open Payments Export with additional fields related to site contact information to meet all your reporting requirements.

Usability Enhancements
The general usability enhancements provide a more streamlined user experience that includes updates to hide/unhide columns functionality, filtering, and much more.

Import & Export Enhancements
Allows for secure importing of contact's NPI number and payee bank data for a quickier setup process.

Rave Site Payments Knowledge Space

GROW WITH US

WEBINARS & VIDEOS

Hot Topics in Clinical Finance

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

Translating Your Protocol into Clinical Financial Management

Clinical Trials Arena Article: How a well-planned clinical trial budget can help prevent burning bridges

How Sponsors and Sites Can Achieve a Harmonious and Optimized Site Budget Negotiation Process White Paper

BLOGS

Site Dissatisfaction and Challenges in Clinical Trial Financial Management

Clinical Trial Financial Management: How to Manage Global Tax

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

If you missed us at the Mediata NEXT NY event, check out the financial management breakout session here.

Join the Clinical Trial Financial Management team at SCOPE in Orlando, FL, on Feb 6-9. Register here.