MEDIDATA

POP

Power of Partnership

ISSUE 01

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

POP ISSUE 01 CONTENTS

POP VOICE

The Financial Effects of Site & Patient Burden

by Shelley Douros

We have all heard that COVID-19 has produced numerous changes for patients and sites, including psychological distress, workforce shortages, overall economic impacts, and varying comfort levels related to healthcare. We must understand the potential risks and burdens for patients and sites caused not only by these global influences but also by the personal circumstances that research participants experience. Understanding burdens to sites and patients visually lets the industry budget accordingly and plan for preventative and protective measures.

There are many factors that contribute to patient burden, site burden, or both, so it is necessary to understand these influences and predict their financial impact. As Dr. Joel Ebuh, CEO and Site Director, Gadolin Research states, "as we observe the surge in gas prices, we must recognize that our industry will not be immune to sustained inflationary pressures. We should anticipate the increased opportunity cost for research participants could lower study enrollment and retention rates."

Meet the patient where they are

Sponsors, sites, and technology providers are responsible for encouraging the industry to collaborate and develop effective ways to meet patients where they are. In addition to the obvious items in the protocol, the cost to patients for things like taking time off of work and providing daycare for their children needs to be understood and compensated accordingly. Research patients are, firstly, humans who thrive on being cared for and heard. As organizations in research and healthcare, our intention is not only to recruit participants but also to retain those clinical trial patients throughout the study duration. The concept of patient burden as it relates to study budgets lets us maintain a mindset of patient-centricity, from the earliest stages of financial planning.

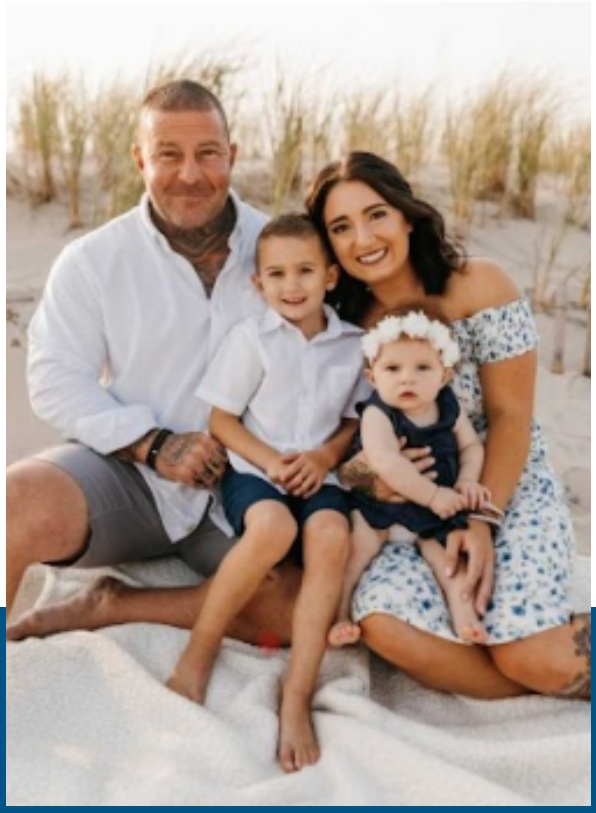
Focus sites on patient care, not administrative tasks

It is imperative to support the allocation of additional budget to serve clinical trial patients better and fund sites appropriately. We have found that administrative tasks slow down study progression and often are the source of dissension between sponsors and sites. Reduce the guesswork and let sponsors create fair and appropriate budgets upfront by having visibility into the patient and site burden values. Presenting a valid budget to a site—in which you've properly considered the effort that a study will consume—can decrease the time and rounds of negotiation, and eliminate tension that arises in the negotiation process.

It is essential that sponsors, CROs, technology providers, and sites partner to increase awareness of each party's experience and therefore understand the goals of everyone involved. Indeed, the study and site budget is a great place to start. By having visibility into patient burden and site burden, the industry can look at the budget from all angles and understand how that protocol and the world around us affect every aspect of the patients being served.

"What counts in life is not the mere fact that we have lived. It is what difference we have made to the lives of others that will determine the significance of the life we lead."

– Nelson Mandela



POP PERSONALITY

CRAIG HOTTER

Craig is an integral part of the CTFM Grants Manager team as the product manager of Rave Grants Manager Planning & Contracting. He has a wealth of industry and product knowledge, having worked in data operations for over 19 years, with 7 of those years at Fast Track before the Medidata acquisition. In April, Craig will celebrate 20 years at Medidata.

Happy Anniversary Craig! We are honored to have you on the product team!

In Craig's previous life, he was a professional football player with the Albany Firebirds. He is an avid saltwater fisherman and a high five expert!

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

Would you rather...

have your dream job or a terrible job that lets you retire in 10 years?
I could adjust to any job knowing I am retiring in 10 years.

eat the oldest thing in the fridge or clean the bathroom?
Clean the bathroom. I am borderline obsessive compulsive.

be famous in your career or celebrity famous?
I am not one for crowds or insincere attention so I'll take a career where I am known for my work ethic and changing lives for the better.

have a super fancy car or house?
Neither is that important to me but if I had to choose I would take a fancy home for my children to enjoy.

have to wear clown shoes or bunny ears every day?
Bunny ears. I have a phobia of clowns!

be a fantastic chef or an amazing driver?
Chef. I enjoy cooking and entertaining. Laws prevent you from driving like Fast n Furious anyway!

IMPACT REPORT

The impacts of COVID on telehealth & remote monitoring

Why are sites seeing up to a 30% increase in site costs?

On January 31, 2020, the US declared a public health emergency. One of the resulting changes was an impact on office visits. Although telehealth visits aren't new, they were not often used. When things changed due to the public health emergency, the Center for Medicare & Medicaid Services created unique telehealth visits and adjusted some old ones. During this time, since telehealth often replaced an actual onsite office visit, the requirements on the clinician increased, which inevitably also increased the cost. Sites saw increases in staff training needs, required technical devices & support, additional software, changes to billing requirements, and overall additional documentation requirements.

How did remote monitoring increase costs during COVID?

In response to the crisis, the industry quickly pivoted to remote monitoring. It was apparent then that many sites still used paper, which resulted in the need for technology and training. Additionally, when monitors went on-site for traditional monitoring visits, they were given access to what they needed and would complete their monitoring in half to a full day with little assistance required. During the height of COVID, instead of the monitor having total access, the site had to proactively collect everything needed for the monitor to complete their monitoring tasks. Because the sites are often required to stay on the phone all day with the monitor to answer their questions, this increased personnel time and increased the associated fees.

HAVE YOU HEARD

The Future of Global Clinical Trial Budgeting: A Story of a Unique Collaboration

Medidata is more than just Rave® EDC, as many already know. The clinical operations solutions are cutting edge and we are always looking for innovative ways to approach the processes and technology, especially within our clinical trial budgeting and site payments solutions. Our recent research showed that an inaccurate initial budget received by the site is one of the biggest pain points within the clinical trial budgeting process. To address this challenge, the Clinical Trial Financial Management (CTFM) R&D team is collaborating with the National Institute for Health and Care Research (NIHR) to understand and improve the frustrations sites, sponsors, and CROs face within the clinical trial budgeting cycle.

The CTFM team is specifically working with Laura Bousfield at NIHR, who leads the organization's study planning and placement support for new research. The Medidata team and Laura have a shared vision and understanding that every day a site contract gets delayed, so does a patient's access to that trial.

About Laura

As an inherently curious person and lover of learning, science gave her answers. Laura was known in her family for asking 'what if…' so undergraduate and postgraduate studies in the life sciences felt like a logical path for her. That led to her first job as Research Administrator in her local Teaching Hospital. This is where she was first introduced to clinical research. She gained hands-on experience in clinical trial patient recruitment, data collection, and conducting visits.

Laura then went to work in Client Services at a Phase I Unit within a global Contract Research Organization (CRO). Looking back, this was her most formative role both in the research sector and professionally. The operations of the unit let her experience research from the initial proposal to the first participant dose through the production of the clinical study report. If science is her yin, then creativity is her yang. She is energized by making, doing, and storytelling. In her work, she channels this through presenting and sharing messages—spanning from attracting new business to shaping the way research is set up to increase patient access across the nation.

The Costing Template is Born

Laura joined the NIHR in 2011. This move fulfilled her ambition to take up a role supporting research in the NHS. She was responsible for a relatively new commercial costing template—a product from an independent review of UK health research funding (Cooksey Report, 2006) recommending a 'standard costing framework.' This framework evolved through the incorporation of user-led improvements under the direction of the multi-stakeholder Commercial Costing Reference Group into the online interactive Costing Tool it is today.

Connection Economy

With the NIHR being a joined-up national research system, it has huge strengths and provides a unique selling point to attract more research for patients across the country. Yet standardized approaches like the Interactive Costing Tool still rely on partnerships working between sponsors, CROs, and sites to embrace the full benefits. Site contracts always involve some level of negotiation; being clear on the starting point and the red lines from the offset will minimize this impact.
The common theme here is connection: According to Laura, "partnerships are critical to my role in supporting the nation's research infrastructure because they all help create and maintain connections; the success of this system is built on the strength of our connections, like Medidata."

Looking to the Future of Clinical Trial Budgeting

The future of global clinical trial budgeting is bright. If we've learned anything, communication and partnerships are key. The only way to improve the process is through relationships and collaboration. The Medidata team is working on some innovative tools. Stay tuned!

To find out more about how the NIHR can support the planning, placement, and performance of your study please contact supportmystudy@nihr.ac.uk Find out more about the interactive Costing Tool on the NIHR website.

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Product Releases:
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June
July
November

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Knowledge Space

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