MEDIDATA

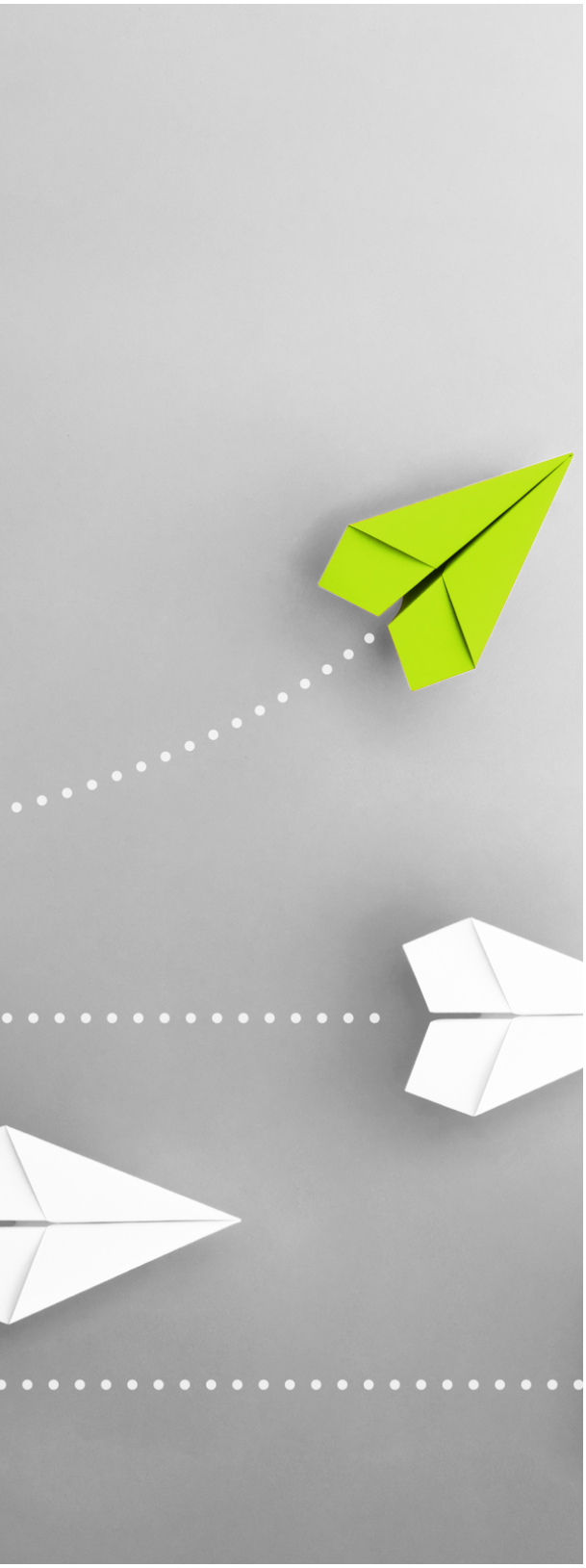
POP

Power of Partnership

ISSUE 05

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

POP ISSUE 05 CONTENTS



POP VOICE

Dr. Mimi Choon-Quinones

Interview by Tina Mincher

Leave a better world for future generations

'We are all going to be patients someday, if not already, and we have a social and ethical responsibility to leave a better world for future generations!'

'Dr. Mimi Choon-Quinones is the Chairman, Board of Trustees at Partners for Patients NGO (PFP.NGO), serving 193 United Nations Countries For Non-Profit. She founded the organization in 1990. Her first partnership over 30 years ago was with The International Lions Club and New York City Schools serving Glaucoma Patients. Over the years, she also worked closely with The African Enterprise to help educate HIV orphans, including supporting a food, medical, and orphanage program. Recently, her research included partnering with Sub-Saharan African medicinal military leaders to spur policy-shaping to support healthcare infrastructure improvements in Uganda, specifically to find the cure for Burkitts Lymphoma and Blood Cancer. Mimi has worked in Pharma for +25 years at Merck, Novartis, and Roche.

Most recently, PFP.NGO accepted a nomination to partner with the European Commission project EU Patient-Centric Clinical Trial Platforms EU-PEARL, representing patients to explore the transferability and generalizability of EU-PEARL into African countries as an opportunity to support low and middle-income countries (LMICs) in building up their clinical trial infrastructure and capacity.

Mimi is passionate about advocating for patients and caregivers by improving healthcare policies, advancing medical knowledge, and driving innovative digital solutions to increase medical access to treatments for patients, especially in the most marginalized regions of the world.

Medidata's Clinical Trial, Financial Management Team, is very proud to partner with Dr. Mimi Choon-Quinones on PROJECT C.A.R.E. (Collaborate to Advance Research Excellence), helping to modernize the healthcare and clinical research system so that no patient is left behind no matter what race, religion, socio-economic status, political affiliation or geographical area by using modern connectivity models, empowering and incentivizing ownership and the sharing of information for business and compliance sustainability.

What inspired you to establish Partners for Patients?

My grandmother was the first female congresswoman in Taiwan. She advocated and proposed legislation to help females who experienced domestic violence access free urgent medical care. However, the Yuan (Taiwan) Parliament never adopted her proposal.

What would you say is your most significant achievement so far?

Established a bilateral collaboration with Dr. Gayo, the President of the Pan-African Parliament, to provide free clinical trial education to every medical doctor in all 55 African countries. The collaboration occurred on April 28, 2023.

What lessons have you learned from the challenges you have overcome?

Don't accept no as a final answer.

How important is the Medidata CTFM collaboration to yourself and Partners for Patients?

Our collaboration with Medidata CTFM is one of the most significant partnerships for patients across the globe. In our efforts, we mutually prioritize the modernization of clinical trials to help patients and sites.

With the incredible goals you have accomplished so far, what else do you want to achieve?

Continue to strengthen our partnership with the Pan-African Parliament and Medidata so that the trust, relationship, and reliability of each other's resources are dependable for patients and society to benefit.

Dr. Mimi Choon-Quinones is a true inspiration with her vision and success of PFP.NGO and the change she is making to improve the lives of millions who might not have access to the medicine they deserve. Thank you, Dr. Mimi, for everything you do, and long may it continue. CTFM is thrilled to make a genuine difference with PFP.NGO.

For more information on Partners for Patients and Project C.A.R.E
For additional detail on CTFM Resources | Medidata Solutions

"It is better to take many small steps in the right direction than to make a great leap forward only to stumble."

~ Louis Sachar

POP PERSONALITY

Abhijit Diwan
Abhilash Kuchipudi
Afreen Sawant
Ajeet Sisodiya
Ajit Chougule
Akash Mohite
Anshu Ojha
Balajiraju Venkataraju
Bhushan Emekar
Chidanand Tripathi
Chinmaya Dehury
Dilyan Georgiev
Faizan Ahmed Siddiqui
Hitesh Mirchandani
Justin De Passos
Karthick Kanagaraju
Kosala Gangaiah
Mandar Tikale
Manisha Dhotare
Nidhi Agrawal
Palash lambhate
Payal Tripathi
Piyush Bist
Punit Pandit
Sangram Shende
Saran Vasudevan
Sathish Kumar Rajendran
Sharayu Patil
Shivendra Shrivastava
Shubham Singh
Sridara Narayanaswamy
Srinivasa Venkatesh
Suresh Reddivari
Swapnil Bhase
Tom Milner
Tushar Vikram Kumar
Unis Beig
Vasavi Killari
Vishal Mahajan

Every single team member across our engineering, test, and PMO teams meaningfully contributes to our shared success. This team has gone above and beyond to support key product deliverables in our March and May Payment releases this year.

They have demonstrated perseverance, collaboration, ingenuity, and flexibility. Our vision to provide a differentiated end-to-end clinical trial financial management experience to our customers is only possible through the daily contributions made by every team member. I am immensely grateful and proud to be part of this CTFM team."

- Meghan Harrington, VP, Clinical Trial Financial Management

IMPACT REPORT

Translating your protocol into a financial forecast

by Shelley Douros

What does forecasting for clinical trial investigator grants encompass?

When thinking about clinical trial forecasts, I often describe them as translating one language into many dialects. The clinical trial protocol is the primary language, and the protocol components, such as data management and biostatistics, are the dialects. Today, we are talking about the dialect of clinical trial investigator grants. It's important to remember that investigator grants cannot be translated by simply looking at the schedule of assessments. When translating the protocol language into the investigator grant financial dialect, builders must read through the entire protocol, including the footnotes. By doing so, the builder can establish a clear understanding of the following components: indication, phase, standard procedures, personnel time, standard visits/cycles, ad hoc procedures, ad hoc visits/cycles, complexity, locations, site costs, invoices, screen failures, dropout rates, and timelines.

What data do I need to bring together?

Besides clearly understanding the clinical trial protocol, builders need a mechanism for obtaining fair market value (FMV) for all the items described above to benchmark the protocol-specific investigator grant accurately. The key is to pay a fair amount for services performed. One great example of FMV is buying a house. When you purchase a home, you first need to understand the comps. And because FMV is not a single value, the comps fluctuate based on location, economy, and quality of schools. Similarly, FMV for grant budgets can fluctuate based on country, site, and investigator.

Are there implications to taking shortcuts?

Before obtaining a protocol, asking for an estimate for a potential study is not uncommon. In this case, you can undoubtedly use estimated costs based on similar previously performed studies. However, once you have the protocol, there are no shortcuts. Suppose you do not accurately vet your protocol or use a trusted data source. In that case, you will undoubtedly miss something, and the financial implications could be costly, and almost always cause study timeline delays.

What are the benefits of using advanced technology that can forecast?

In the example of buying a house, a real estate broker is often hired to help you better understand the comps in the neighborhood. Yes, independently, you can look up recent sales. Still, because you are not a broker, you are limited in the amount of publicly available information. So, you will need more details to understand exactly why the home sold at that specific price. In the same way, to accurately create and forecast an investigator's budget, you need a comprehensive FMV tool that allows you to benchmark with confidence, especially when creating a budget for a new indication, location, or site. With the correct tools and database, the builder can design and report defensible holistic, and accurate budgets. For example, there are plenty of COVID-19 studies now. However, a little over a year ago, there were no COVID-19 studies to reference for creating a forecast. Using sophisticated benchmarking tools that gather and mine internal and external data is imperative to ensuring accuracy and compliance. Without a technology with proven expertise, you are left blinded, which not only skews your budget but also increases timelines and delays start-up.

What technology capabilities are critical to producing an accurate forecast for the life of a study?

Forecasting a clinical trial investigator grant budget continues after you build a global or location budget. It also continues beyond the point of site contracting. To accurately forecast, you need to understand things like site start-up timelines, patient enrollment projections, screen failures, and dropout rates, to name a few. Once you begin enrolling subjects, you need to develop your budgets based on actuals and re-forecast based on the most current projections. This must align with your payment triggers and EDC data pull for accuracy. Of course, you'll always have protocol amendments to keep the process even more exciting. It can feel like you're playing a game of "Where's Waldo," but this is why it's imperative to use technology that cannot only surface those crucial data points but technology that can help you aggregate that data. You then want to use the technology that takes it a step further to help you interpret the various data points to complete the financial lifecycle and ultimately allow you to stay on budget and meet required timelines.

HAVE YOU HEARD?

RAVE GRANTS MANAGER

Improve Country-specific Ratios
Grants Manager Planning has modernized and deepened the breadth of our country ratios! Because country ratios are a set of measures to evaluate a country's economic and social status, this feature ensures you have accurate and reliable comparisons to determine the fair market value in today's global markets.

Smart Activities and Other Direct Costs
This Grants Manager Planning feature release will allow for expedited and confidence in activity and other direct costs selections based on industry trends and usage. Updates through product to reflect name change (Industry Usage %). Users will also engage with current AMA content to enhance their best practices knowledge.

Croatia Conversion Reconciliation
Croatia has adopted the EURO as of Jan-01-2023. Grants Manager will update to reflect this adoption. The Croatian Kuna has been retired effective the upcoming Q2 data release.

RAVE SITE PAYMENTS

Spain and Turkey Local Language and Currency Options
Having local language in multiple areas of the product allows for a better user experience and coherent data display for sites. These language and currency enhancements can be found in Payments Reports, Site Payee Portal, and Site Invoicing sections of the product.

Enhancement to Study Costs and Payments Export
The costs and payments export report will now include the approved date and approved by for each line item. This provides better visibility and the ability to enhance payment planning activities.

Ability for Bulk Update and Download
This update allows the ability to mass download RFI/PFI documents, and conduct mass status changes. This feature streamlines and speeds up the workflow allowing to update site invoices in ‘ready to send’ to the next status within site invoicing.

Manual Addition of Withholding Tax in Site Payments
Having the ability to add Withholding tax manually. Tax (rates and codes) can be manually added by the user allows for user convenience with submitting invoices with Indirect and Withholding tax to streamline the invoicing process.

For more product information, visit the knowledge space

Rave Site Payments Knowledge Hub

Rave Grants Manager Knowledge Hub

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
- 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
- Clinical Trial Financial Management Resource Page

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

Podcast:

- Collaborating for Transparency: Site Budgets & Payments