# Day 1, Patient 1

## How Sponsors Can Overcome the Growing Challenges in Clinical Trial Budgeting and Negotiation

This paper seeks to explore the most crucial obstacles to successful budget design and negotiation in light of the current complexity experienced across the clinical trial universe. It highlights how technology can streamline these traditionally manual, time-consuming workflows, increase transparency and predictability, and deliver more current, and accurate data for an optimized study start-up.

## Contents

## Assessing the Budgeting Landscape

In the race to get critically needed drugs to market, every study sponsor/CRO, globally, seeks to arrive to Day 1, Patient 1 as quickly as possible, without sacrificing the robust study and budget design necessary for a fair and site-championed clinical trial agreement.

Budget design and negotiation is a complex process in and of itself. It needs to account for both sponsor/CRO and site requirements and expenditures, and also reflect the local fair market value for its constituent costs and line-items.

There are numerous obstacles to arriving to fair market value and additional challenges that accompany the iterative budget negotiation process. But alongside those challenges, sponsors must also negotiate the growing complexity of clinical trials.

This complexity is bringing budget creation and negotiation issues to the forefront as a critical source of potential delay. It also makes it increasingly evident how crucial it is to innovate solutions and practices to remove the growing roadblocks to a timely and well-designed study launch. **Each day that a trial is delayed can result in losses up to $8 million.**[1]

> “
>
> Study startup through activation remains one of the most inefficient cycles facing clinical development operations.
>
> *- Ken Getz, Professor Tufts CSDD*

Why are delays in finalizing budgets growing longer? Why is it so difficult to agree upon the terms of a budget if all the stakeholders are working toward the same goal of FPI?

First, let’s examine four key challenges that pervade the industry and often impede the achievement of a timely First Patient In (FPI) milestone.

- Out-of-Date and Inaccurate Grants Payment Data
- Inefficient Processes Leading to Delayed Timelines
- Difficulty Accommodating Global Regulatory and Budgeting Nuances
- Payment Execution Misalignment

# Out-of-Date and Inaccurate Grants Payment Data

**Data Reliability**

was identified as the **#1** budgeting challenge.[2]

Just **27%** of sponsors and CROs are satisfied with the current data that they have available for building their investigator grants budget.[6]

It may seem obvious that creating an accurate budget requires access to accurate data to ensure fair reimbursement to sites, or fair market value (FMV). And yet the lack of valid or robust financial data is often cited as one of the biggest obstacles to forecasting costs. Why is the benchmarking we all rely upon to create a fair initial budget sometimes miles away from what the trial site feels is fair to implement a study?

For starters, there is no single, credible source of accurate negotiated investigator grants data available to sponsors and CROs. And the information that does exist is often outdated or incomplete - a key reason that data providers today require manual data input from redacted agreements and often receive minimal data from customers (sponsors), resulting in a limited data set. Inaccurate data not only fail to support regulatory and compliance requirements, they put the entire budget in an indefensible position.

Despite the fact that start-up fees have been trending upward globally for years, current industry benchmarking often lags woefully behind. They reflect low and outdated costs that may take years to catch up. Benchmarked administrative fees, in particular, are often stunningly out of sync with real-world costs. Without reliable FMV, budgets are built that are not indicative of industry standards.

If parameters based on "FMV" do not come close to reflecting what trial sites are requesting, rounds of negotiations, escalations, documentation, and justification will ensue, potentially resulting in problematic agreements that disincentivize sites. What can be done to increase confidence in the accuracy of data?

## SUMMARY

**What Contributes to Unreliable Data?**

- No single, credible source of information
- Outdated and fragmented data
- Inaccurate benchmarks
- Global pricing variables

# Inefficient Processes Leading to Delayed Timelines

Process inefficiencies abound in study startup and play a key role in prolonging cycle times, which have been trending longer in recent years. In fact, in the past ten years, the average cycle time required to achieve agreement between parties has increased by one full month. While the definition of an appropriate cycle time may differ by sponsor or CRO, too often, getting sites up and running means chasing ever-shortening timelines.

One of the main sources of process inefficiencies can be found in the budget negotiation process itself. Sponsors and sites typically engage in countless back-and-forth negotiations conducted via email and spreadsheets to arrive at a negotiated budget. These manual communications occur not only *between* sponsors and sites, but also *within* the sponsor and site organizations, before either party even arrives at the negotiation table. When you factor in the wait time between each email exchange, you may encounter a frustrating series of delays.

While some delays that lead to timeline adjustments are beyond your control, others—such as factoring in holiday time when a site is closed—are foreseeable. To build out your timeline, it helps to know the standard practices of a given country, region, or institution. A particular site may have internal escalation processes that add to overall anticipated time to agreement, such as the requirement that several stakeholders sign off on a contract before providing an initial response to a Sponsor. Or a site may be supporting multiple studies simultaneously and must prioritize study activities internally.

Unfortunately, longer start-up directly increases enrollment timelines, decreasing the number of months of enrollment at the target rate.[3] Knowing what's needed to efficiently negotiate and execute a budget can avoid costly timeline delays and help keep your study's start-up phase on schedule.

> The processes are very slow and manual and primarily done by email.
>
> *- Elisa Toma, Chief Executive Officer, CTA Focus*

Over the past 10 years, site start-up **cycle times have increased by 1 full month.**[3]

## SUMMARY

**What Causes Timeline Delays?**

- Extended cycle times
- Manual negotiation process
- Timeline adjustments
- Opaque internal site activities

# Difficulty Accommodating Global Regulatory and Budgeting Nuances

Despite living in a global society, there is no universal playbook for global investigator grants budget development. Differences in regulatory requirements, standards of care, and budgeting nuances from one country to the next all contribute to a highly complex environment, which can slow the path to achieving FPI. Some common global variances and the budgeting challenges they present are discussed here.

**80%**

of applications for drugs and biologics to the FDA contain data from studies outside of the United States.[4]

In some countries, regulatory requirements mandate there be a fully negotiated budget *before* regulatory submissions. If your budget isn't fully negotiated in these countries, your submission will be delayed or rejected. And since some regulatory authorities meet infrequently, missing your targeted submission deadline means having to wait until the following available submission date to resubmit.

The implementation of a study can also vary widely by country. Some countries have very complex requirements related to the sourcing of a study drug. Others may require different routes of administration for that drug within a clinical setting. A drug that is normally administered orally, for instance, may need to be administered via infusion to minimize patient risk. Take paracetamol, for example. In oncology trials, paracetamol is typically administered as an oral pre-medication; in France, it must be administered via infusion. Infusing pre-medication results in added pharmacy preparation costs as well as additional patient and site personnel time during each treatment visit.

Another challenge with negotiating budgets globally is the variance in country-mandated budget templates, which makes it challenging to customize budgets for country-specific needs. Adding to this complexity are translation issues and cultural differences, which can affect the meaning, tone, and cadence of your communications.

What if you didn't have to track these various country nuances? What if you had readily accessible information on requirements for regulatory submissions, country budgeting practices, contracting standards, and timelines scaled by country or site? What impact could having such information make on the accuracy of your budget?

## SUMMARY

**How Do Global Nuances Impact Budgeting?**

- Timing concerns of EC submissions
- Variance in country-specific study implementation
- Differing budget templates and formats
- Language barriers and translation needs

# Payment Execution Misalignment

Finally, let's look at a challenge that represents the most important component of having a budget properly negotiated and finalized: payment execution. Budget planning and payment execution are intrinsically linked. According to Kyle Cunningham, Chief Product Officer at Greenphire: "In order to be really good at payments, you need to understand budgets...and to master budget planning, you need to understand payments." And yet despite the importance of timely payments, sites typically wait an average of 5 months to be paid.[5] Why does this happen?

One key obstacle to ensuring timely payments is the time and effort required to split budgets. Most budgets are split manually, which is labor-intensive. And many countries require that budgets be split according to country custom, which is complicated. In Belgium and the Netherlands, for example, departmental splits are the norm, while in Russia and Ukraine, the Principal Investigator and site each receive percentage splits. Defining department/payee splits can be very challenging, particularly without a solution that automates the process.

Other factors that confound the payment process include cross-currency payments, the need for pre-invoice validation approval from certain sites, and the tax implications of payments. Certainly, when it comes to global studies, taxes are a significant and non-negotiable component of your budget. And yet, too often, taxes are not discussed until the first invoice appears, leaving sponsors scrambling to reconcile payments. What if there were a solution that laid bare tax components and imported them directly into the workflow? With the ability to build tax into a global investigator payments solution at the outset there would be less need for realignment and reconciliation later on.

In assessing your own budget build, ask yourself how your budget currently accommodates payments. Do you have the ability to customize payments for country-specific splits? What if you didn't have to manually split budgets? What if you weren't forced to add unnecessary amendments that resulted in rushed negotiations and inadequate payment terms? Think of what this could mean in terms of accelerating FPI.

**5 Months**

The average time is takes for sites to be paid.[5]

If sites can't get paid based upon what is negotiated in their contracts, then all the work leading up to contract execution is for nothing. Goodbye FPI.

*- Catherine Click, Director Clinical Pricing, Greenphire*

## SUMMARY

**What Complicates Payment Execution?**

- Department/payee splits
- Possible pre-invoice validation approval
- Cross-currency payments
- Tax implications

About **80%** of sponsors and CROs feel there is a need to improve tools/ technology to enable more effective and efficient study start up processes.

**80%** of those who invest in study start up technology report time savings.[7]

## A Vision for the Future of Clinical Trial Budgeting and Negotiation

While the current model is unsustainable, the future of clinical trial budgeting and negotiation is bright. But what *does* the future look like? It encompasses a comprehensive disruption of the status quo, visionary products and tools, and trusted partnerships. It is through innovative technology that clinical trial stakeholders will be able to eliminate the barriers to effectively and efficiently arrive at an agreed upon budget.

New technology is in fact available, opening the door for much-needed process and data improvement. Greenphire's EnvisiX™ is a clinical trial budget solution that centralizes and streamlines budget creation and negotiation. With a combination of an intuitive workflow and access to current investigator grants payment data, EnvisiX delivers efficiency and accuracy for an optimized study start-up. Through a direct integration with the industry-leading site payment solution, eClinicalGPS, EnvisiX pairs budget planning and development with site invoicing, payment execution and tracking in a seamless, closed-loop workflow.

The result? Sponsors and CROs can generate a more accurate budget, accelerate the time to FPI and relay the agreed budget into automated and timely investigator payments via a single portal. Ultimately, sponsors and CROs can improve efficiency and clarity throughout the financial lifecycle, resulting in stronger site relationships and a better trial experience.

> **EnvisiX** can accelerate study start-up by eliminating the guesswork and streamlining budget build and modification processes.
>
> *- Jim Murphy, CEO, Greenphire*

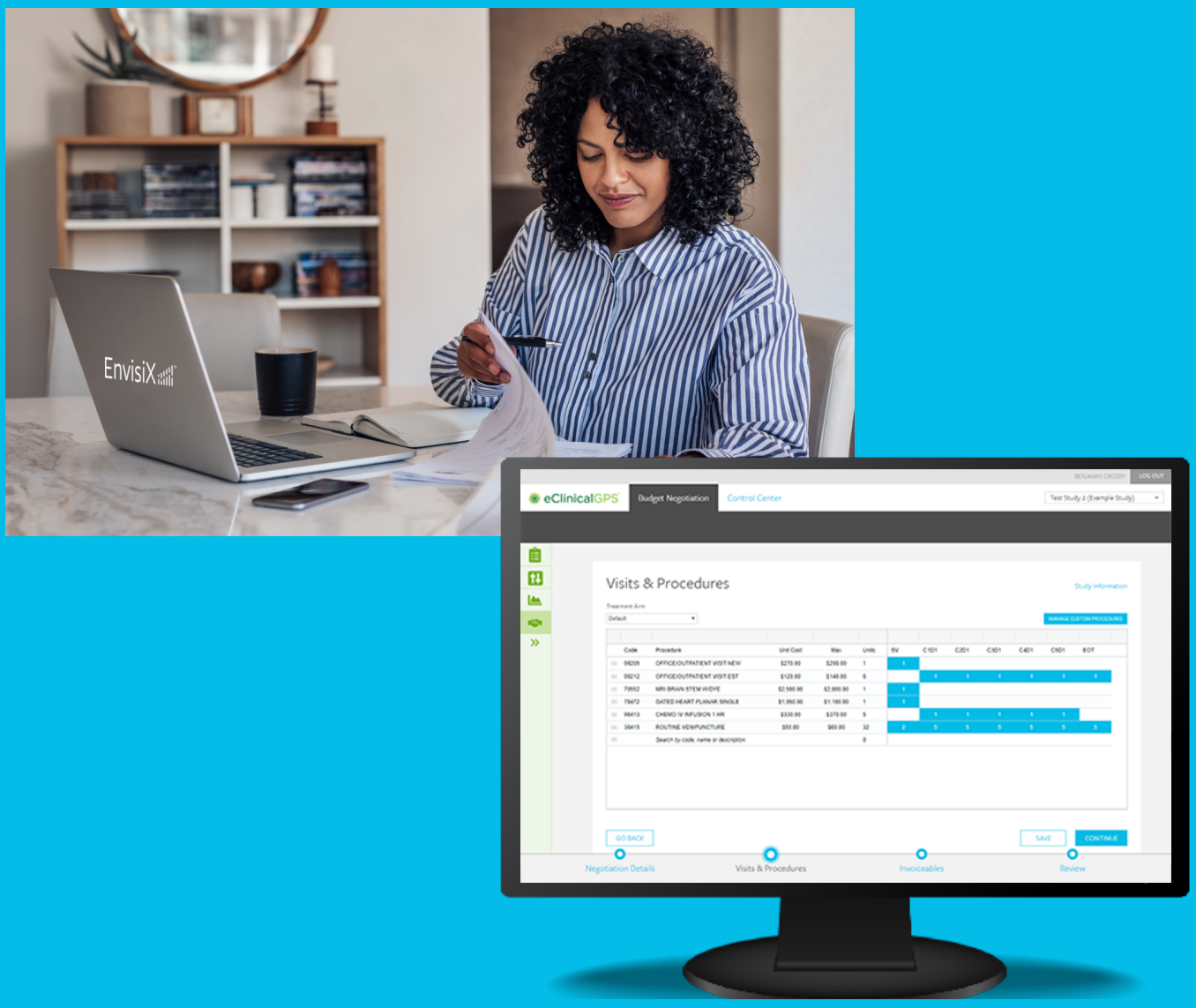
# The Technology Advantage: Transforming Study Startup

| Budgeting Challenge | EnvisiX Solution | Benefits to Sponsors and Sites |
|---|---|---|
| Unreliable data | Up-to-date, accurate negotiated investigator grants payment data | Improve budget accuracy and site relationships |
| Process inefficiencies/ delayed timelines | Intuitive portal that streamlines the budget creation and negotiation workflow, providing complete transparency across stakeholders | Accelerate study timelines and increase workflow visibility |
| Global nuances | Centralized, translated platform that is reflective of real-time global investigator payment data | Navigate global variances in budget templates, formats, languages and Fair Market Value (FMV) |
| Payment execution alignment | End-to-end integrated workflow from budget creation and negotiation to global payment execution | Optimize the financial and administrative lifecycle through a singular comprehensive platform |

# Get to know EnvisiX

Greenphire understands the complexities of translating clinical trial protocol requirements into a meaningful budget. Learn more about how EnvisiX can transform your budget build and negotiation workflow and integrate with our site payments solution, eClinicalGPS, for end-to-end financial lifecycle optimization. Experience smarter trials from day one.

Greenphire.com/budgeting



# Sources


1. Clinical trials and their patients: The rising costs and how to stem the loss. Pharmafile. Available at: http://www.pharmafile.com/news/511225/clinical-trials-and-their-patients-rising-costs-and-how-stem-loss. Accessed July 29, 2020.

2. Webinar quick poll. Conducted on June 19, 2020, by Greenphire.

3. Optimizing site start-up in oncology trials: practical and creative strategies to improve cycle time, control cost, and maintain quality. Medsource website. Available at: https://medsource.com/wp-content/uploads/2018/07/Optimizing-Site-Start-Up-In-Oncology-Trials-Presentation.pdf. Accessed July 28, 2020.

4. FDA perspective on international clinical trials. Available at: https://www.fda.gov/media/91849/download. Accessed 7/11/20.

5. Tate W, Hilty L. Sponsor payments to sites: a new award to recognize timely payment. J Clin Res Best Prac. 2017; 13(6). Available at: https://www.magiworld.org/Journal/2017/1706_Award.pdf. Accessed 7/11/20 perspective on international clinical trials. Available at: https://www.fda.gov/media/91849/download. Accessed 7/11/20.

6. Greenphire Survey, October 2020

7. Wide inconsistency observed among clinical trials' startup time: Tufts report. Available at: https://www.fiercebiotech.com/cro/wide-inconsistency-observed-among-clinical-trials-startup-time-tufts-report. Accessed January 24, 2018.

EnvisiX™

Powered by greenphire

Smarter Budgeting from Day One

Learn more:

Greenphire.com/EnvisiX