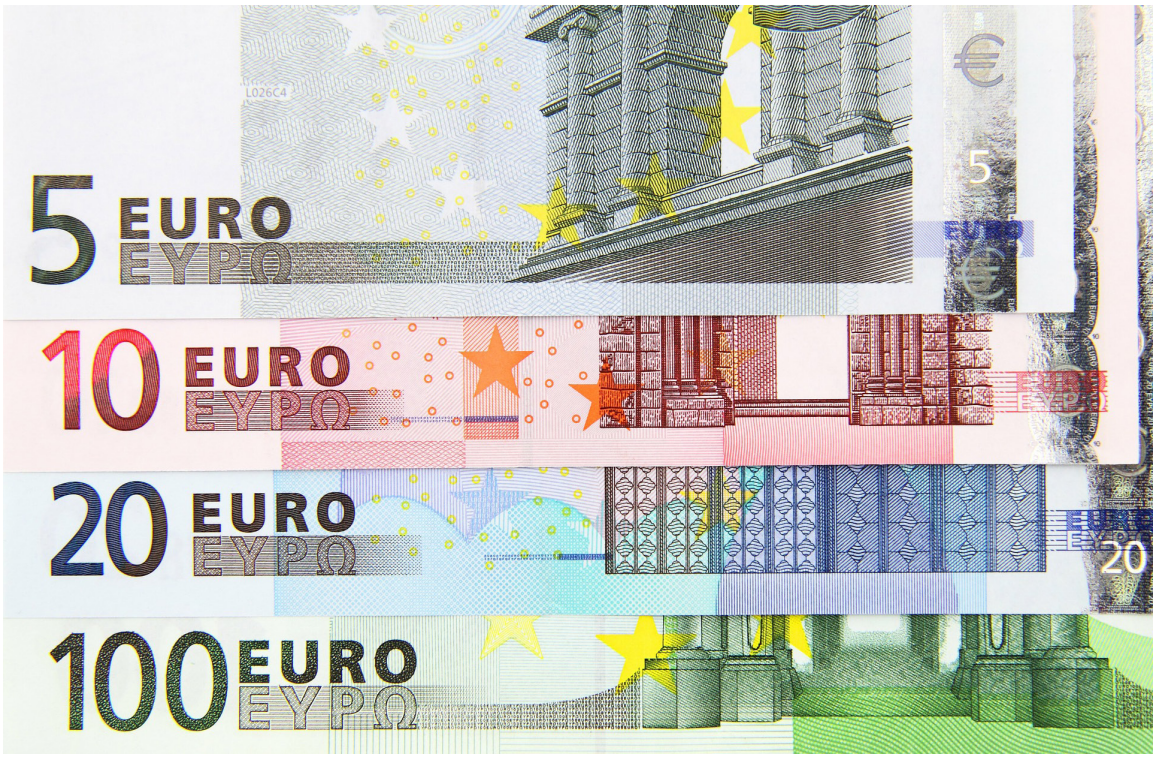
Enhancing Payment Workflows

With the challenges currently facing sites, participants, and sponsors regarding clinical payments in the EU, introducing technology may optimise payment workflows and ultimately standardise processes across all clinical trial stakeholders

Jim Murphy at Greenphire



Groundbreaking R&D innovation is yielding an increasing number of candidate treatments and clinical trials, many of which are targeting precise patient populations. The clinical research ecosystem is facing new pressures as a result, elevating the urgency for industry to take action aimed at better supporting investigative site success, making clinical trial participation more convenient for patients and ensuring the necessary financial visibility, predictability, and control needed for all stakeholders to make informed decisions.

While the actions required to adapt to these industry dynamics are not limited to any one functional domain, the need and opportunity for change is most evident in the business administration side of clinical research. In this domain, most activities are still performed using manual spreadsheet-based processes or bespoke tools that address only small components of a broader set of interconnected business processes.

Since clinical business and financial processes exist at the intersection of sponsors, CROs, sites, and patients, they have a direct impact on all clinical research stakeholders. As a result, lack of payment workflow connectivity impacts payment

> It is ultimately up to each country to interpret and implement these guidelines in accordance with their own national laws

timelines, frequency, process efficiency, and payment accuracy, all of which add financial stress and administrative burden to sites and patients.

The current reality is that sites around the world face clinical payment workflow challenges that impact the quality and efficiency of their work – from negotiating a budget to reimbursing participants, and from invoicing for work completed to reconciling payments. In fact, approximately half of European investigative sites recently surveyed by the Society of Clinical Research Sites spend a minimum of four hours per study per month on invoicing activities, and one in four sites outside the US spend seven hours or more on these tasks. Equally concerning is that, without automation, sites typically spend between 20 and 50 minutes per patient per visit processing reimbursements or arranging participant travel. Resource-intensive, manual activities associated with participant reimbursements and site invoicing result in reduced accuracy, have limited financial transparency, and create unnecessary administrative burdens, ultimately distracting from the investigative site's preferred focus: research and participant care.

The good news is that the tide is turning thanks to the advent of new technologies that optimise payment workflows, increase financial visibility, and accommodate tax and regulatory requirements for unique processes, addressing the needs of clinical trial stakeholders across regions, countries, and cultures.

The Current State of Payments

Financial and administrative challenges in EU clinical trials are influenced by many factors, including fragmentation, differing work processes and business models, regulatory challenges, and financial transparency.

Fragmentation

With increasing R&D spending and exciting new biotechnology innovation, studies are, more than ever, spanning geographic borders, cultures, and currencies. According to WHO's International Clinical Trials Registry Platform, there are more than 100,000 clinical trials taking place in Europe alone.

While beneficial for sponsors, the research community, and patients whom the research outcomes and therapies will ultimately serve, conducting research across a nonsynchronous landscape places a substantial administrative burden on sponsors and sites. Despite efforts to harmonise within Europe, as well as globally, locational variance in regulations, cultural norms, health systems, and languages create an inconsistent and often inefficient clinical trial environment.

Previously, no single technology platform existed that could reconcile the regional, cultural, multi-regulatory nature of EU clinical trials from a financial and administrative perspective. EU sites and sponsors now have access to technology that enables a holistic approach to financial operations, including the ability to configure based on unique study/market needs – global budget processes, streamlined payment execution, and access to localised information. These technologies help countries across the EU address the current fragmentation by introducing smart, configurable, time-saving workflows.

Differing Work Processes and Business Models

Due to cultural differences and site preferences between, and even within, EU countries, processes and expectations may differ significantly (an example being the variance of invoice workflow practices, a process at the core of investigative site financial sustainability). Four out of five respondents to a recent joint study indicated that reducing the need to create invoices manually in favour of a more automated invoicing process would be extremely or very beneficial. Site payment frequency is another critical ingredient in site financial sustainability and is often less frequent than desired because of the site invoicing process, as a side-effect of the inefficiency. Making the invoicing process easier for both sites and sponsors is fundamental to addressing the payment frequency issue in the EU. The study also demonstrated

that infrequent payments continue to be a primary hurdle for many sites, negatively impacting their operating budget and their ability to appropriately resource clinical research.

Identifying solutions that can support any desired payment frequency allows for sponsors and CROs to cater to various site types and regions with differing needs. The ability to unlock more frequent payments enables sites to better fund their operations, which may include additional investment into activities such as recruitment, enrolment, participant engagement/retention efforts, and other areas that may boost operational efficiency.

Invoicing is not the only issue faced by sites: the entire manual payment process lacks clarity. All too often, sites receive payments and don't have visibility into what that payment is for, resulting in increased administrative reconciliation efforts. When you break down the complexity involved with site payments, it is easy to see why traditional manual processes with multiple handoffs take longer and drain resources. Purposefully built solutions that automate and streamline the entire site payment workflow support accurate, compliant, transparent, and timely monthly payments. Sponsors and CROs that implement such solutions can truly enable site sustainability and success by improving site payment practices. This added efficiency becomes especially meaningful for sites managing multiple studies where a significant portion of their revenue and costs are attributed to clinical research.

Regulatory Challenges

Regulation impacting clinical trials in the EU is complicated by a fragmented landscape of processes, geography, stakeholders, and languages. However, in recent years, numerous pieces of guidance have been issued to help promote greater consistency while continuing to ensure that clinical trials are conducted in a safe and effective manner, with the participant experience and privacy held in the highest regard.

The EU has taken steps to unify laws, regulations, and administrative procedures for clinical trials. This began in 2001 and was further illustrated in 2014 when the EU issued directives to set quality requirements and create transparency among member states conducting clinical trials involving human participants. The EMA plays an additional key role in ensuring that the standards of GCP are applied.

However, it is ultimately up to each country to interpret and implement these guidelines in accordance with their own national laws. As a result, the legislation and practice regarding participant reimbursement for direct expenses, as well as for time and inconvenience, vary to some extent throughout Europe. The most common practice requires that any compensation is reviewed and approved by the respective ethics committee. Generally, reimbursements of out-of-pocket clinical trial expenses are supported in almost every country across the European continent. However, many in the industry are unfamiliar with the rules and regulations related to participant reimbursement and take an overly conservative and non-participant-centric approach, making it harder to address the increasing time and travel burdens that are derivative of today's highly targeted studies.

The enactment of these regulations has spurred pharmaceutical companies and research sites to take a closer look at their operations to ensure they are maintaining compliance. Leveraging technology and the resulting transparency of processes help sponsors and sites deliver on the regulatory requirements. Additionally, providing documented materials that outline compensation models and methods have proven effective in working with ethics committees across the continent.

Apart from clinical trial legislation, the enactment of the EU GDPR has dominated headlines. GDPR strives to harmonise data privacy and usage across Europe. While there are new requirements organisations need to adhere to, the healthcare sphere has historically been held to a higher standard than other industries through strict process regulation. Nonetheless, empowering EU citizens to have more control on how their personal data are handled presents mandatory operational changes for the clinical trial sector. It is imperative that sites and sponsors work with experienced, trusted vendors to document processes, collect data, and provide an audit trail to show patient consent. While implementing formal documentation and building GDPR-compliant processes may be an undertaking for those involved, the focus drives trials towards a patient-centric approach that makes good business sense. Sponsors and CROs are finding that, by implementing technology solutions, they are optimising site processes while ensuring regulatory compliance and control.

Financial Transparency

There are numerous complex expenditures that go into

conducting clinical research. Pharma companies currently spend $125-$160 billion annually on global R&D, with clinical trials making up about half of that amount. Without an efficient way of tracking spends, the lack of transparency into how these funds are actually dispersed increases the risk for redundancies and loss. Sponsors and sites across the EU are moving towards prioritising clinical trial payments as its own budget item, with an emphasis on improving financial control and visibility. By centralising global patient reimbursements, investigator payments, and travel support, sponsors can ensure that payments are executed consistently, accurately, and in compliance with financial regulations around the world. Sponsors and sites are more actively seeking partners with the expertise and flexibility to manage these global business and regulatory needs in support of a more sustainable and site-centric model.

The use of business intelligence and proactive spend assessment capabilities to support clinical trial budgeting is becoming a stronger and more powerful tool. There is a growing desire for better insight into clinical trial data trends that can help predict data flow, timelines, costs, outcomes, etc. Using technology solutions, sponsors will have far more accurate data for enhanced control, visibility, and forecasting capabilities that allow them to be more effective stewards of their capital and plan for future studies.

Major Trends Transforming Administration

Though many of the changes in EU clinical trials – and the technologies developed to address them – are driven by regulations, there are other factors at play.

Digital Transformation

Digital transformation is happening in the healthcare sector, albeit perhaps less rapidly than other less regulated industries. Technologies are advancing the way healthcare professionals receive, process, and communicate information. One of the most critical transformations is the transition from painfully manual tasks related to financial management and administration to streamlined, transparent workflows. Technology solutions are enabling clinical trials to be conducted more efficiently and cost effectively, ultimately resulting in higher-quality data and better outcomes. The realised benefits span all clinical trial stakeholders from sponsors and CROs to sites and participants.

Patient Convenience

According to studies, the average dropout rate across all clinical trials is around 30%, and 85% of clinical trials fail to retain enough patients (1). Out-of-pocket costs and the inconvenience of participating in clinical trials breed financial toxicity that leads to poor recruitment and retention. As such, there is a push in the industry to drive towards a more patient-centric approach, focusing more on patient care and implementing programmes and solutions to enhance the participant experience for increased engagement.

One area in particular that continues to be a hurdle for participants is travelling to the research site. As trials become more complex and patient populations become increasingly specialised, study participants must often travel greater distances and spend more time at clinics than ever before, creating severe hardships for participants who are in suboptimal health. Managing the logistics of travel (flights, trains, hotel stays, etc.) can be a top reason as to why patients drop out of a trial or do not participate at all.

On top of dealing with, at times, complex travel, participants must worry about out-of-pocket costs associated with getting to the clinic or overnight stays. With the patient-centric approach in mind, implementing solutions that can address these logistic and financial roadblocks faced by participants is key to sustaining successful clinical trials. Technologies can allow for streamlined travel arrangement that completely removes the burden of booking from the participant and the site. In addition to travel arrangement, out-of-pocket costs can be eliminated, enabling the sponsor to pre-fund the programme, taking care of any costs the participant may otherwise have to front.

By reducing the hurdles associated with taking part in a clinical trial, participants can focus on solely that – being in the clinical trial. With solutions that simplify logistical processes and related costs, they are provided with peace of mind and can be more engaged in the study. With participants at the heart of clinical research, patient centricity is the key to sustaining clinical research success.

Adoption of New Technological Innovation

Change is the only constant in clinical research today. Identifying patients with an increasingly narrow criteria and then retaining these patients as they continue through a longer, more complex clinical trial process has prompted pharma companies to adopt patient and site-centric policies

and investigate new digital strategies to enable them.

Taking the best possible care of patients is what will ultimately drive retention and deliver the highest quality data to the sponsor – a virtuous cycle that empowers the rapid development of new medicines and the advancement of human health. In the end, it is the sites that adopt best practice approaches and streamline processes that will be able to consistently provide the best care and achieve the highest performance results, ultimately giving them access to more study choices. The most attractive sponsors will be those who minimise business financial and administrative burdens for sites and provide them with empowering tools.

Mature technologies plus operational guidance in using these tools are the keys to providing the breakthrough. The benefits that payment automation workflows can deliver to trials, such as increased patient retention rates and enhanced engagement, as well as streamlined internal processes and improved financial intelligence, have never been more important. Ultimately, these new specialised technologies improve process efficiencies for all stakeholders and enable consistency across multifaceted EU studies.

As Greenphire's CEO, Jim Murphy leads the strategy for the company, including client satisfaction, business operations, commercial execution, and financial performance. Jim is committed to fostering a culture of growth, innovation, excellence, and employee satisfaction. He has focused his career on building innovative eClinical software companies to address challenges and unmet needs in the global clinical research ecosystem. Prior to joining Greenphire, he most recently served as the President and Managing Director of Almac Clinical Technologies, where he was responsible for strategic, financial, and operational leadership.

References

1. Visit: vertassets.blob.core.windows.net/download/64c39d7e/64c39d7e-c643-457b-aec2-9ff7b65b3ad2/rdprecruitmentwhitepaper.pdf