CLINICAL LEADER

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Site Payment Systems And Processes for The 21st Century

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How friendly and productive would your workplace would be if you consistently delayed employee paychecks by 100 days or more – with no late payment fees? And when you do get paid, the amounts are inconsistent and lack any explanation of what (or when) it is for. No reasonable business or employee would accept such terms.

Yet, it is common for investigative sites to wait four months or more to collect payment for clinical trials. Then the site often must perform additional administrative work to determine what the payment is for, reconcile the amounts, and deal with discrepancies. The result is financial stress and dissatisfaction for sites, potential study delays, and additional costs for the sponsor and the site. In the meantime, site staff has spent so much time and energy on tracking down payments and managing bills that they have had less resources available for recruiting patients and managing the trial.

In a recent international survey of more than 750 investigators, the top two burdens reported were completing contracts and regulatory documents, and getting paid on time.[1]

What can be done to solve this problem, improve site satisfaction and motivate performance? The following considerations for managing global site payments are critical:

Process, Regulatory and Technology Challenges

Integrate Dynamic Payment Systems with Other Systems

Increasingly complex study designs and global study conduct affects not only clinical conduct, but also the associated budgets, milestones and payments. Integrating payment system technology and processes with other study systems increases efficiency and minimizes error.

A report from the Tufts Center for the Study of Drug Development (CSDD) indicates 69% of all trial protocols have at least one amendment.[2] In addition to all the other ramifications, amendments that occur in the middle of a study require investigator payment systems that can accommodate midstream changes that may or may not be retroactive. In addition, similar functionality is required as sponsors or CROs sometimes modify the fees paid to sites during the course of a study.

Handle Multiple Site Payees

Outside North America it is not uncommon for the investigator, pharmacist, radiologist, etc. to be paid separately, sometimes with different addresses and payment distribution schedules. The A/P staff and payment system must be able to efficiently handle the individual payment streams and provide easily accessible consolidated reporting.

Comply with Government Reporting Requirements

Aggregated payment reporting for health care providers continues to grow globally, with the Sunshine Act (aka 'Open Payments') in the U.S. just one of several examples.

With the U.S. Sunshine Act, otherwise referred to as "aggregate spend," the requirement is for consolidation of payment data at the healthcare provider level, which equates to the investigator level as it relates to research. The challenge with this requirement is that grant payments for clinical trial research are typically made to investigative sites – the payees – rather than to the physicians themselves.

Requirements outside the U.S. are continuing to develop, at both the country level and through large influential associations like the European Federation of Pharmaceutical Industries and Associations (EFPIA). This association includes more than 40 European based pharmaceutical companies and over 30 country member associations. It has established requirements that all corporate members of EFPIA disclose certain transfers of value to healthcare professionals and healthcare organizations as of 2016 regarding transfers in 2015.

These reporting requirements represent another disruption to traditional practices to the clinical operations model. Disparate data sources combined with the manual processes on which many organizations rely to track crucial information make it quite difficult and labor

intensive to collect and accurately report aggregate spend data in accordance with Sunshine Act requirements as well as the specific transparency requirements of each country and/or associations like EFPIA.

Solutions

Centralize Payment Administration

Centralizing payment administration simplifies payment and reporting processes, as well as cash-flow forecasting and funding. In a global study, payment through national banks may make sense or even be required to facilitate the payments process according to local practices, but management and data should be centralized. In addition, centralized computer systems are easier to manage and integrate with other systems, e.g., Electronic Data Capture (EDC).

Automate Payment Triggers

Now that EDC is widespread, it is practical for the EDC systems to communicate most payment-related events directly to A/P systems.

In most cases in the U.S., investigator grant visit payments do not involve the physical raising of an invoice by the investigator site. Payments are generated by assessing completion of subject visit milestones as indicated by a number of data sources, most preferably EDC. The rationale is that grant payments should be tied to work performed, which is primarily indicated by completed visits (or some variation) in the EDC, CTMS, IVR system, etc.

In addition, triggering payments on unmonitored EDC data allows for accelerated cash flow for the site, as the trigger is now tied to the site's action of inputting the EDC data versus the sponsor/CROs monitor schedule. This process also serves as an incentive for the site to ensure their eCRF data is input into the EDC system in a timely fashion as there will be a direct correlation between their data entry and payment.

The risk in this approach is minimal because systems can be administered to capture study-to-date trigger activity to ensure any changes in the data are processed correctly. Additionally, a 2013 TransCelerate study determined that 96.3% of data remains unchanged once entered into the EDC system, further demonstrating that paying on unmonitored data presents a very nominal risk.[3] With electronic funds transfer, sponsors can now pay sites, particularly in the U.S., in near real time, with remittance advices that detail exactly what activities are covered. This increases investigator satisfaction and the financial health of sites.

Process Invoices Required by International Legislation

In the U.S., sponsors (and CROs) routinely process Investigator Grant payments without invoices from sites. Internal, “shadow” invoices help sites reconcile receipts to billable activity. However, outside the U.S. tax and accounting regulations require sites to raise invoices.

This ROW invoice process introduces additional levels of complexity and burdens on payment processors and associated A/P systems. It is often a challenge for sites to reconcile their activities as indicated via the EDC with their contracts and payment schedules, and the activity can be quite burdensome.

The process is a bit backwards. It encourages purpose-built environments to drive standards and efficiency, while incorporating the flexibility to manage inherent site- and country-specific challenges. An example of this complexity is highlighted with the payment to multiple parties being the norm in Eastern Europe. Ideally, sponsors and CROs should be leveraging the performance data from their EDC while also ensuring the site is in agreement with their submitted invoices.

VAT and Indirect Taxes

As the number of global trials increases, it is critical that site payments are handled by considering factors that affect the applicability of local taxes, especially Value Added Tax (VAT).

With the notable exception of the U.S, nearly every country has a VAT system, making it an inevitable consideration for a global study. As a result, sponsors need to structure the Clinical Trial Agreement (CTA) appropriately to avoid unnecessary financial costs. Depending on the country, considerations such as the location of the contracting party and the currency of payment can affect whether a site should charge the sponsor VAT on top of the budgeted fee.

A well -planned tax strategy and full oversight of the trial process will help manage tax risk and ensure compliance with local regulations. Local standard VAT rates vary by country, but the global range is between 5-27%, meaning a significant potential outlay on investigator payments.

Deploy Capable Personnel

Increasing volume and complexity requires capable personnel to deploy and operate payment systems in a reliable and systematic manner. Deployment processes must be rigorous, since automated systems can turn small mistakes into big problems. Automated systems must be supplemented with manual exception handling, which requires not only

A/P expertise but also some understanding of the operational and quality management aspects of clinical studies, as well as knowledge of local practices and cultures with respect to the payment processes where the sites are located.

Conclusion

Timely and accurate payments to research sites help enhance conduct by those research sites. Sophisticated payment systems and processes play a fundamental role in successful clinical research. Ancillary benefits include more accurate and efficient regulatory reporting, more efficient use of capital, smaller A/P staffs, and better management visibility. We're already 16 years into the 21st century, so it's time to replace those 20th century systems and processes and use proven technology to improve the investigator payment process.

References

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