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"Happy Trials to You"

Solving the Problem of Slow Payments to Sites By Laura Hilty, Shaun H. Williams, and Norman M. Goldfarb

Clinical research sites rely on timely payments by their sponsors and CRO customers. Unfortunately, many sites struggle financially because the typical payment process in the clinical research industry is remarkably slow compared to that in other industries, which results in sites having to front payment obligations to employees, landlords and study participants before they are compensated for their efforts. While many sponsors and CROs recognize the inadequacy of their payments system, only some have improved their payment timelines.^{1,2}

Four factors principally drive the average payment period to sites:

- The contractual payment obligation, often quarterly, paid 45 days after the end of a quarter, and based on monitoring of the site's work
- The timeliness of the sponsor's or CRO's approval of a payable event, such as monitoring of a study visit
- Timely payment after the end of a quarter
- Issues that require resolution before payment can be made

In 2017, Wendy Tate, Director of Analytics at Forte, analyzed over 60,000 payment records from participating clinical research sites for the MAGI Award for Excellence in Site Payments.^{2,3} She found a *median* payment period of 66 days after a payable event but a *mean* payment period of 140 days. (Figure 1, next page). This difference between the mean and median averages was due to a long tail in the distribution of payment periods: While 65% of payments were made within 90 days after a payable event, 35% were paid later, with 7.5% paid over a year after the event. (These findings do not include "holdback" payments, which are typically due after the conclusion of a site's work on a study.)

In November, 2017, 120 site and sponsor personnel responded to a Forte and Syneos Health survey on the causes and effects of extremely delayed payments.⁴ Survey results indicated four common reasons for payments to exceed 120 days, in order of importance:

- Approval processes, especially when multiple approvals are required
- Invoicing problems, e.g., invoicing errors and reconciliation of invoices against work performed
- Contract structure, e.g., complexities in the payment obligation that require manual processing outside the payment system
- Clinical trial agreement (CTA) amendments, e.g., contract execution and alignment with actual study activities

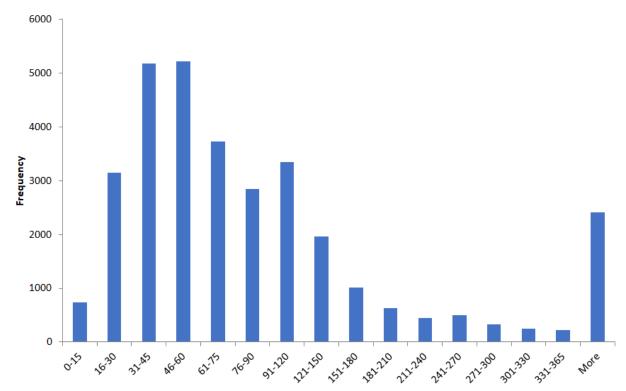


Figure 1. Payment Terms

Improving the Site Payment Timeline

Sites can take the following steps to improve their payment timelines:

- Work with sponsors and CROs that pay in a timely manner
- Negotiate fair and clear payment terms in the CTA, including interest on late payments
- Establish expectations, contacts and processes with sponsors and CROs
- Record all payable events in a clinical trial management system (CTMS)
- Send invoices in a timely manner
- On a weekly basis, monitor payment status and follow up with sponsors and CROs on delayed payments
- Create and follow a standard operating procedure (SOP) for collecting on payments, including how to handle amendments
- Track payment performance by study, sponsor and CRO, and address deficiencies.

Sponsors and CROs can take the following steps to improve their payment timelines:

- Recognize the importance of a timely payment process for building a network of high-performing sites
- Assign ownership of the payment process to an appropriate manager or executive
- Simplify and standardize payment arrangements
- Establish clear lines of communications with sites for payment issues
- Create a payment processing system that supports timely payments and has the flexibility to handle various contractual payment obligations
- Make payment data transparent to sites, including detailed remittance advices and visibility into the status of pending payments

- Minimize payment approval levels (e.g., with only one approval required for most payments)
- Automate payments that meet certain criteria, e.g., for qualified sites, automatic payments triggered by data entry into the sponsor's or CRO's EDC system
- Identify and communicate to sites the reason for delayed payments
- Establish a clear, consistent, transparent and timely process for addressing payment issues, with special attention to long-deferred payments
- Survey sites for satisfaction and their perceived issues
- Track payment performance and address deficiencies

Sponsors and CROs benefit from strong relationships with high-performing sites. High-performing sites that are financially healthy can afford to invest in high-performing personnel, technology and quality management systems to sustain and improve their performance, as well as reduce sponsor and CRO costs, such as for site monitoring and data cleaning. In addition, sites will naturally give their primary attention to sponsors and CROs that are good partners.

The current slow and inefficient payment systems are costly for sponsors, CROs and sites. More timely and efficient processes can reduce these costs, improve the financial health of sites and help sponsors and CROs complete their studies successfully.

References

- "Aligning Data Entry and Site Payment Incentives For Clinical Trials and Patients," Linda B. Sullivan and Keith W. Dorricott, Applied Clinical Trials, September 2017, http://www.appliedclinicaltrialsonline.com/aligning-data-entry-and-site-payment-incentives-clinical-trials-and-patients
- 2. "Forte Presents Winners of the Fall 2017 MAGI Award for Excellence in Site Payments," Forte Research Systems, November 2017, https://forteresearch.com/wp-content/uploads/2017/11/Forte-Presents-Winners-of-the-Fall-2017-MAGI-Award-for-Excellence-in-Site-Payments.pdf
- 3. "Sponsor Payments to Sites: A New Award to Recognize Timely Payment," Wendy Tate and Laura Hilty, Journal of Clinical Research Best Practices, June 2017, http://www.firstclinical.com/journal/2017/1706_Award.pdf
- 4. "Examining the Impact and Solutions to Extremely Delayed Site Payments from Sponsors," Anna Hrovat-Staedter, November 2017, https://forteresearch.com/news/infographic/examining-impact-solutions-extremely-delayed-site-payments-sponsors

Authors

Laura Hilty is Vice President of Product Management at Forte. Contact her at laura.hilty@forteresearch.com.

Shaun H. Williams is Sr. Director, Investigator Management Solutions, Clinical Solutions, at Syneos Health. Contact him at shaun.williams@syneoshealth.com.

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.