

Insights into global clinical trials transformation

Bayer Healthcare US (Bayer) has expanded the Automated Site Payments and Invoice Resolution (ASPIREs) program that it initially codeveloped with Ernst & Young LLP (EY US or we) to further improve clinical trial site relationships and drive industry-leading practices.



For Bayer, the first step to improving relationships between sponsors and sites was to assess the current state challenges and the underlying causes of manual, burdensome work for sites. After recognizing that many sites operate at a financial deficit during clinical trials and face significant administrative burden, Bayer conducted a comprehensive review of its site management processes and identified site payment improvements as a focus area.

Following the success of the US pilot of the ASPIREs program, Bayer evaluated site payment processes across Europe (including Germany, Spain, Bulgaria, Austria, Finland, Netherlands, France, the United Kingdom, Czech Republic, Norway, Belgium and Portugal), Asia-Pacific (including Singapore, South Korea and Australia), Canada and Mexico. The purpose of this assessment was to further identify opportunities to enhance payment efficiency, timeliness and accuracy to ultimately strengthen Bayer's site relationships, enable better-informed decisions and contribute to its goal of becoming a preferred clinical trial site sponsor. Downstream, these site payment improvements targeted three key actions: reducing administrative burdens for both Bayer and its clinical sites, increasing site payment transparency by utilizing an automated site payment portal and improving compliance reporting for closeout.

The design and build phases for the automated site payment program revealed nuances within some countries' site payment processes due to local regulations, languages and taxation. For example, some sites, such as the one in Portugal, are not able to invoice on their own. And in Belgium, sites can initiate a self-billing process. Further, the local health authorities in Singapore mandate specific payment terms, while in Bulgaria, sites and health care professionals (HCPs) a variance in payment terms and guidelines. Sites in Mexico also saw nuances around health authority regulations due to government regulations on utilizing a site payment portal.

On a wider scale, one of the unexpected benefits the EY US team found from mapping the entire current state process from end to end is that greater insights into budgeting and contracting identified critical touchpoints, including clinical trial agreements are worded and how the site's budget and protocols are established. When the EY team mapped out the end-to-end process, we discovered how Bayer could improve everything from contracting on the front end to compliance reporting at the back end.

Given these insights, Bayer sought the EY US team's help in transforming its clinical site invoicing and payment approach to new countries and regions. To achieve this goal, Bayer focused on addressing three key pain points:

1

Reliance on manual processes

Bayer's current state process required manual effort to cross-reference site activities against the original contract and budget, leading to often duplicative templates and data entries.

7

Lack of transparency

Tracking and reporting invoice and payment statuses across multiple data sources caused additional difficulties in achieving payment accuracy. As such, reporting and cash flow impacted clinical site reimbursements.

3

Inconsistency in timeliness of payments

The added time and effort required to complete the invoicing and payment process frequently led to delayed payment statements that were difficult to understand.



Implementing an automated payment process for our clinical sites at Bayer has greatly improved our internal efficiencies and payment cycle times to sites, leading to overall increased site satisfaction.

Geri Masessa

Director in Resource Management, Bayer

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Maximizing automation and transparency across the globe with an automated site payment solution

Bayer and EY US expanded and deployed the ASPIREs program to 18 countries.

After an in-depth examination of Bayer's processes and an understanding of future state goals, Bayer and EY US codeveloped ASPIREs to address Bayer's challenges on four fronts:

1

Process efficiency

Reduce inefficiencies in Bayer site management and, ultimately, for sites and clinicians in parallel. 2

Transparency

Provide real-time reporting on invoicing and site payment statuses with increased transparency.

3

Site satisfaction

Enable timely, accurate payments and reduce payment disputes to improve site satisfaction.

4

Resource allocation

Utilize third-party services and payment analytics to drive efficiencies by eliminating manual tasks and duplicative efforts.

Benefits for sponsors around using a solution that facilitates expedited and reliable payments to sites

Clinical trial sites that leverage this solution experience heightened confidence about working with pharma.

The ASPIREs program enabled Bayer and its clinical trial site partners to drive an expedient, streamlined clinical trial process. Among the improvements seen in nearly 20 countries around the world, Bayer's average cycle time for payment to sites dropped from 43 days to less than 32 days. As such, the company was able to easily meet its payment date obligations, provide an automated view into outstanding payments, and increase the satisfaction of HCP

and clinical trial site management. By reducing the administrative burden around payment processes, Bayer was able to pay sites more quickly and reliably.

These results highlight significant efficiencies in the Europe and Asia-Pacific regions, with improvements in process in several countries that have complex requirements and regulations, as discussed above.

2,600+	sites and HCPs enrolled in the ASPIREs program for automated payments	71%	less time spent supporting payment processes
13,000+	payments made to sites/HCPs successfully so far across the 18 international countries	58%	less time spent performing invoice or payment dispute resolution activities
< 4.0%	average rate of invoice issues among thousands of quarterly payments	50%	less time spent tracking site payments

The calculations of US site payment program efficiencies are documented in the US Case Study <u>here</u>.

Automation has driven clear efficiencies and time savings for Bayer. Ultimately, it is a differentiator in the marketplace that enhances Bayer's customer service capabilities. As Bayer continues to act on its commitment to become a preferred sponsor, it enables clinical trial sites to focus on what's most important: driving access to cutting-edge therapies and revitalizing patient care.

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