WEBINAR SUMMARY

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Pharma Ignite | SCRIP CITELINE COMMERCIAL

Innovative Approaches to Clinical Trial Financial Management

Presenter:
Zahiah (Zee Zee) Gueddar, Senior Director, Commercialization, IQVIA Technologies

Meredith Landry, Managing Editor, Custom Content, Citeline (Moderator)

KEY THEMES

- In clinical trials, financial management affects site satisfaction, costs, and go-to-market schedules.
- Protocol amendments, rising interest rates, and geopolitical unrest are increasing clinical trial costs.
- Sponsors, site coordinators, and patients face different financial challenges during clinical trials.
- To support financial management, sponsors want modularity, suite orchestration, global reach, and access to emerging technologies.
- The future of financial management requires a smart solution that is orchestrated from end to end.

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OVERVIEW

Clinical trials are becoming more complex and costly, as the number of international sites, participants, and protocol amendments grows. These trends are creating increased pressure for efficient, technology-enabled financial management in trials. Adopting an end-to-end financial management solution creates a better trial experience for all key stakeholders—from sponsors to site coordinators and patients.

IQVIA's Financial Management Suite offers a coordinated set of capabilities with global reach, access to emerging technologies, and the flexibility of SaaS and hybrid services. The result: an accelerated path for bringing life-changing products to market.

CONTEXT

Zahiah Gueddar discussed how IQVIA Technologies provides clinical operations leaders with the flexibility needed to manage the entire financial lifecycle. She reviewed the capabilities of IQVIA's end-to-end Financial Management Suite.

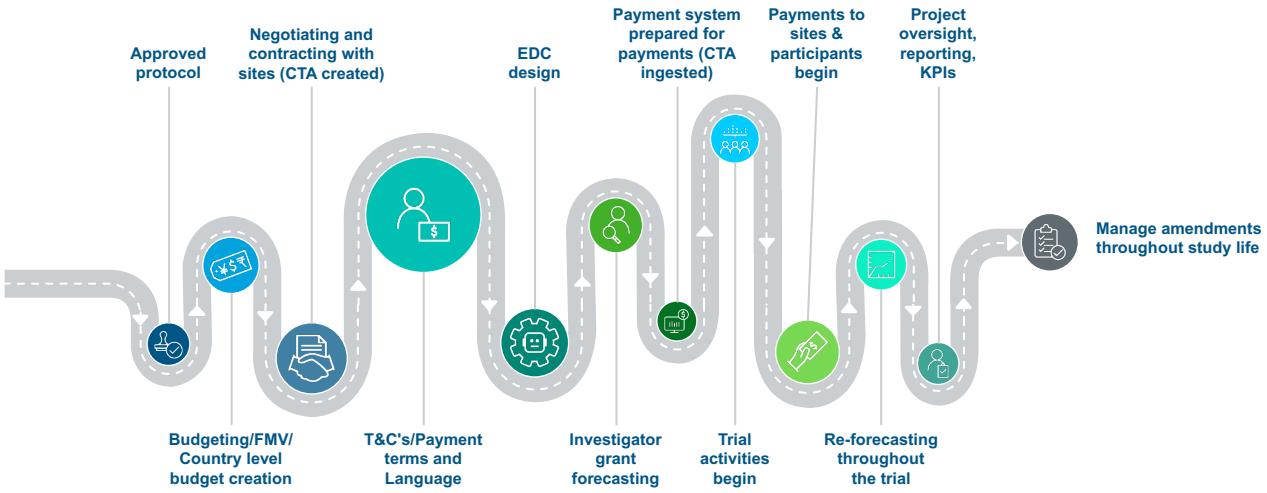
KEY TAKEAWAYS

In clinical trials, financial management affects site satisfaction, costs, and go-to-market schedules.

The financial management process for clinical trials is complex and includes many touchpoints. Key challenges include:

- **The cost of touchpoints across the study lifecycle.** Half of clinical trial costs consist of investigator payments. For a global study with sites in multiple countries, millions of dollars often must be tracked. To ensure efficiency and accuracy, the right process and technologies are needed to manage funds throughout a clinical trial. Research shows that the per-day cost of a phase 3 trial is $55,000. When considering financial management in clinical trials, the financial impact of study delays can't be ignored.
- **Slow cycle times.** The burden of manual data entry is high when it comes to financial management of clinical trials. Automating that work speeds payments to sites and participants. Protracted budget negotiation processes can also delay sites from getting started. For many sites, payment disbursement rates are a major pain point. As many as 40% of clinical sites drop out of studies due to payment delays.
- **Global complexity and constraints.** Trials are getting more complex as the number of countries, variety of sites, and volume of participants grow. As a result, it's essential to understand the regulatory landscape as it relates to site and participants payments. It's also critical to truly offer fair market value (FMV) to sites.
- **Visibility and reconciliation.** The entire financial process must be transparent so stakeholders have the necessary data frequency and precision for forecasting. Sites want visibility into where their payment is within the process and what the spend profile looks like.

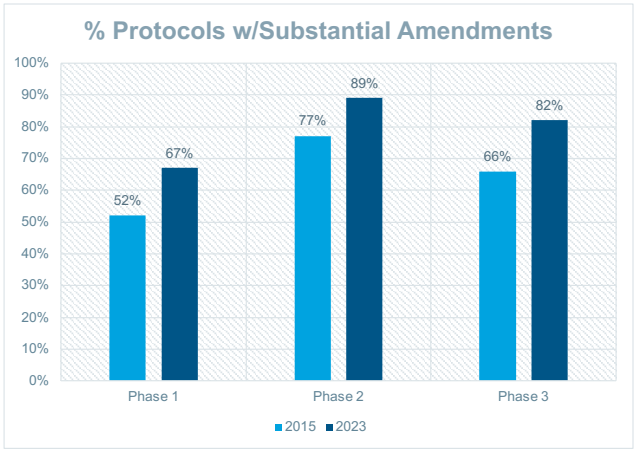
Figure 1: The Financial Management Process for Clinical Trials

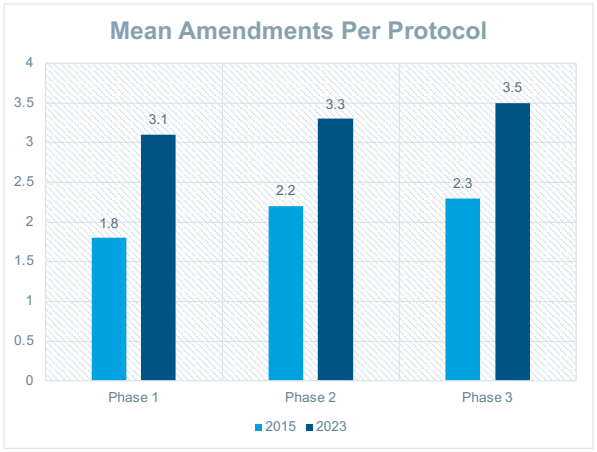


Protocol amendments, rising interest rates, and geopolitical unrest are increasing clinical trial costs.

Protocol amendments are a pain point and a reality in clinical trials today. Between 2015 and 2023, the prevalence of amendments increased nearly 60%, with 80% of all late-stage Phase 3 protocols averaging 3.5 substantial amendments.

Figure 2: Protocol Amendments by Trial Phase – 2015 vs. 2023

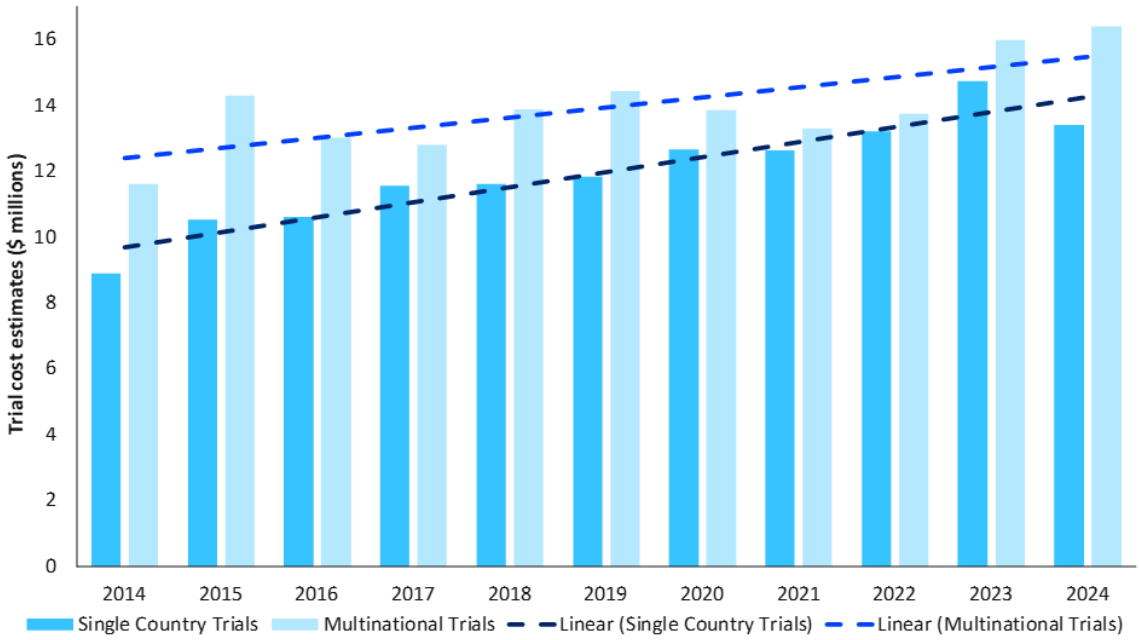




Amendments add complexity and affect every aspect of the financial management process from electronic data capture (EDC) design to contracts, payments, payment adjustments, and more. The more manual and labor intensive a financial management process is, the more error prone it becomes in the face of protocol amendments.

The cost of both single and multinational trials has increased dramatically between 2014 and 2024, so managing expenses has become more important than ever.

Figure 3: The Cost of Single-Country Versus Multinational Trials in the US, 2014-2024



Sponsors, site coordinators, and patients face different financial challenges during clinical trials.

In the world of clinical trials, site success contributes to sponsor success and trial success. Unfortunately, the financial management process creates issues for all the key stakeholders in a clinical trial:

- **Sponsors.** Sponsors assume that various systems and vendors will communicate in a harmonious way, which is rarely the reality. Working with different teams, vendors, and CROs adds complexity to financial management. In addition, sponsors are overburdened with site complaints about visibility into payments and negotiation of fair market value. Change orders are another concern.

> "One of the most common complaints that IQVIA hears from sites is they're overloaded with technology. For a single sponsor, a site may need to log onto 40 different technologies or tools. Simplifying that for sites is very important."
>
> *Zahiah Gueddar, IQVIA Technologies*

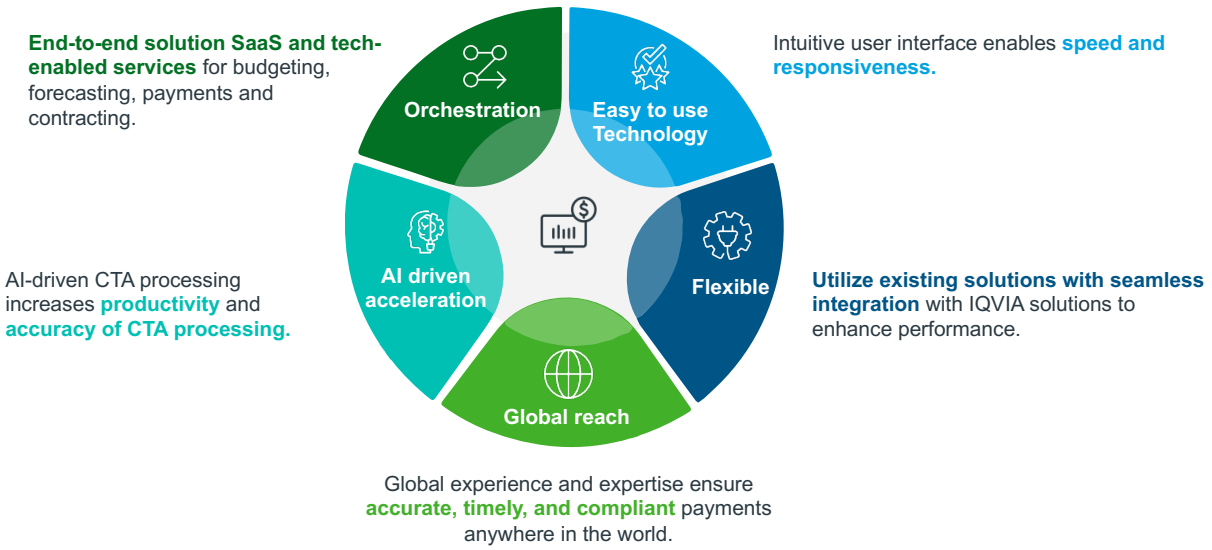
- **Site coordinators.** This group assumes that payment information will be transparent, but that's not always the case. Site coordinators may be unable to see where their payment is or they may have trouble logging into portals. Payment delays cause stress and burden, since some sites can't float cash for long periods of time.
- **Patients.** It's essential to pay trial participants in near real time. Patients should never be in a position where a financial burden deters them from participating in a clinical trial. Any technology that participants interact with must be intuitive.

To support financial management, sponsors want modularity, suite orchestration, global reach, and access to emerging technologies.

Four trends IQVIA is seeing among sponsors are:

1. **SaaS and hybrid services.** More sponsors want modularity and optionality. Some want to insource financial management, while some want to outsource, and others want something in between. Vendors must offer SaaS for sponsors that want to insource. For outsourcing, a combination of SaaS and hybrid services is required to meet requirements related to technology and orchestrated processes.
2. **Suite orchestration.** Among sponsors using a multi-CRO, multi-vendor approach to trials, many want suite orchestration to support financial management. They need one solution to execute site and participant payments, handle forecasting, and create FMVs to negotiate with sites.
3. **Global reach.** More sponsors want the ability to execute globally and make payments in any country. IQVIA offers that level of global reach, so sponsors don't have to develop a multi-vendor payment method or create a solution internally.
4. **Emerging technologies.** AI is a hot topic among both sponsors and sites. Both stakeholder groups want to understand how AI is applied to the financial management process. They are curious how it can help with speed and cost.

Figure 4: Sponsors Demand Differentiation

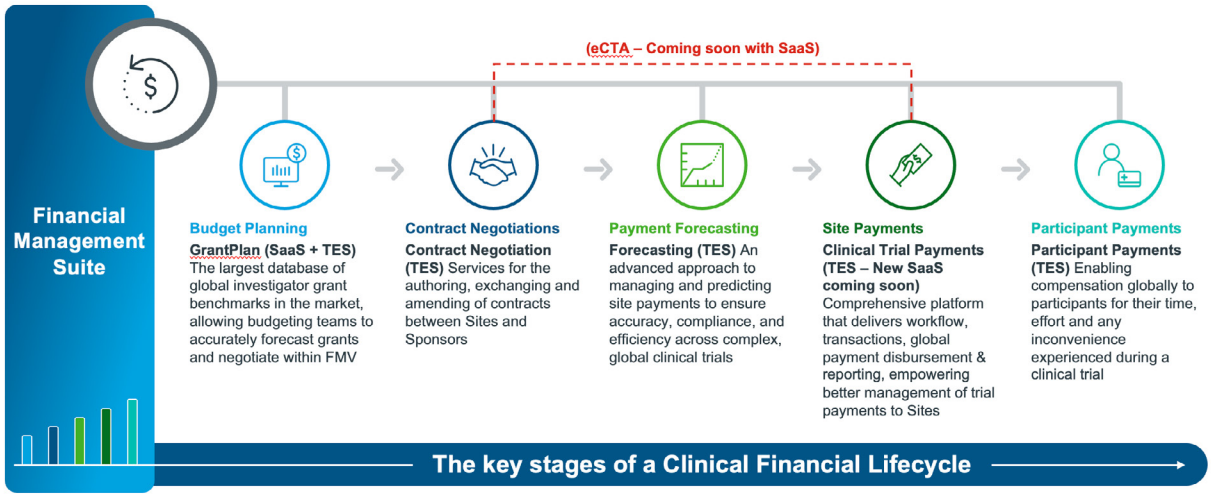


The future of financial management requires a smart solution that is orchestrated from end to end.

The IQVIA Financial Management Suite is an end-to-end clinical trial financial management solution that makes site performance and site success a priority for sponsors. With IQVIA, it's possible to orchestrate the management of complex protocols, support site satisfaction, and accelerate the path to a healthier world by bringing life-changing products to market faster.

The IQVIA Financial Management Suite includes functionality for budget planning, contract negotiations, payment forecasting, site payments, and participant payments. In 2025, eCTA will be released. eCTA is a SaaS offering that will ingest data, not simply from the OCR perspective. AI intelligence will also be used to feed data into the suite payment system.

Figure 5: The IQVIA Financial Management Suite



> "Sponsors need to benchmark in an effective way, so what you're offering your sites is truly fair and your sites are happy with that negotiation. They feel that they are being paid in a fair way and they are happy to execute on the trial contract."
>
> *Zahiah Gueddar, IQVIA Technologies*

OTHER IMPORTANT POINT

- **IQVIA's customer feedback loop.** IQVIA gathers feedback from sponsors and sites in a variety of ways, ranging from customer success team interactions to surveys and focus groups. This input ensures that IQVIA builds what customers want.

ADDITIONAL INFORMATION

- To learn more, visit **IQVIA Technology**

BIOGRAPHIES

Zahiah (Zee Zee) Gueddar

Senior Director, Commercialization, IQVIA Technologies

Zahiah (Zee Zee) Gueddar leverages over 17 years of diverse industry expertise encompassing delivery, finance, operational effectiveness, and the commercial sector. Gueddar offers invaluable insight into the challenges encountered by sponsors, CRO's, sites and patients. In her role leading IQVIA's Financial Technology offerings, she serves as an innovative partner for clients seeking transformative outcomes and growth opportunities. Known as a strategic thinker and problem solver, Gueddar is responsible for driving growth and differentiation, product go-to market & ensuring innovative and competitive offerings. Gueddar is based in Southern California and is a graduate of San Diego State University.

Meredith Landry (Moderator)

Managing Editor, Custom Content, Citeline

Meredith Landry is the Managing Editor of Custom Content at Norstella. She is a seasoned writer, editor, content strategist and moderator. With a career spanning digital media, print publications and live events, she has built a reputation for elevating content strategies and fostering meaningful discussions. Landry has led editorial teams, developed content strategies and produced high-quality publications for major organizations in industries including healthcare, geospatial intelligence, real estate and more. She has managed newsroom operations, produced live and recorded podcasts and served as a conference moderator. Landry has a journalism degree from Loyola University New Orleans and currently lives in Los Angeles, California.