

Rave Grants Manager: COVID Investigator Initiated Studies (IIS) Accelerates Study Start-up

Grants Manager: COVID IIS helps Sponsors determine and negotiate quickly fair IIS budgets. Leveraging Medidata's deep fair market value data and our clinical trial budgeting expertise - we can help you accelerate your site's study start-up by eliminating contracting and budget negotiation delays.

With Rave Grants Manager COVID IIS you can:

-  Develop accurate and detailed site budgets for investigator initiated studies (IIS) - including patient, procedure and site costs
-  Ensure fair, consistent, data-driven investigator payments around the world for COVID-19 vaccination and treatment indications
-  Engage investigators directly to share study budget details, and then review and edit proposed budgets and contracts
-  Mitigate compliance risks in IIS grants with defensible data through an audit trail of negotiation activity
-  Support financial reporting with transaction records readily available for analysis

Delays in site contract and budget negotiations can cause unwanted delays in clinical study execution. Only Rave Grants Manager provides industry-wide negotiated site cost information—which is critical to study start-up and clinical trial success—via an online, collaborative web platform with exclusive access to PICAS.

Accelerate a Key Process in Site Start-Up

Speeding site budgeting and negotiations is a critical factor for success in clinical trials. Rave Grants Manager helps meet key study start-up milestones by:

- Supporting the preparation of optimum budgets
- Improving cycle times when reaching budget and contract agreement with investigative sites
- Using a complexity analyzer to help sponsors determine fair site payments based on relative study complexity
- Replacing e-mail and paper processes with web-based communication for efficient negotiations

RAVE GRANTS MANAGER

Medidata Rave Grants Manager is the site budgeting and contract negotiation solution that ensures appropriate payment and expedited site contract agreements.

It's smart: Rave Grants Manager provides actual negotiated grants and industry benchmarks, allowing you to analyze your company's specific grant history.

It's unique: Rave Grants Manager is the only product on the market that allows you to see protocol complexity, procedure frequency and site-specific costs so you can improve your negotiation strategy.

It's actionable: Rave Grants Manager facilitates payment setup and plugs into the Medidata Rave Clinical Cloud™ platform, providing access to upstream data for faster budget development and downstream data for better study execution.

PICAS

PICAS is the clinical benchmark and cost database of negotiated investigator grants with a store of more than 320,000 grants and contracts and 29,500 protocols for over 1,800 indications. Rave Grants Manager accesses PICAS data to create budgets tailored to specific therapeutic areas, procedures, geographies and indications, while identifying the financial impact of site selection and protocol changes.

Sharing Information to Foster Collaboration

With Rave Grants Manager, clinical, project management, contracting and finance professionals worldwide can forecast project costs, as well as develop detailed trial budgets. Executives can also collaborate on budget details using multiple clinical variables.

The easy-to-view reports confirm key aspects of the grants process: for instance, they indicate whether the budget represents costing informed by industry negotiated benchmarks.

Benchmark Internally

Rave Grants Manager also documents and allows rapid analysis of a sponsor or CROs site agreements and previous contracts. By providing an accessible, historical record of grants, the analysis function assists in **new site recruitment, reduces compliance risk and helps guide standardization across clinical programs**. This also provides documentation of payment specifics for regulatory, audit and negotiation purposes.

Identify and Analyze Complex Trials

Rave Grants Manager includes a powerful tool called the complexity analyzer developed in collaboration with Tufts Center for the Study of Drug Development. The complexity analyzer **calculates benchmarks with industry averages, along with a site's work effort** that procedures, visits and the entire protocol require. This helps sponsors and CROs determine site payments based on relative study complexity.

Site Negotiations Made Easy

Rave Grants Manager provides real-time information on the progress of site negotiation so sponsors or their CROs can take proactive action. Additionally, an audit trail of negotiation activity is retained for reference and compliance with fair market value regulations. Users can configure the fields and values displayed in the negotiation, increasing negotiation flexibility.

THE PLATFORM OF CHOICE FOR CLINICAL RESEARCH

The Medidata Rave Clinical Cloud is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to-end suite of Rave applications. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords, you are now on a truly unified platform.

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

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