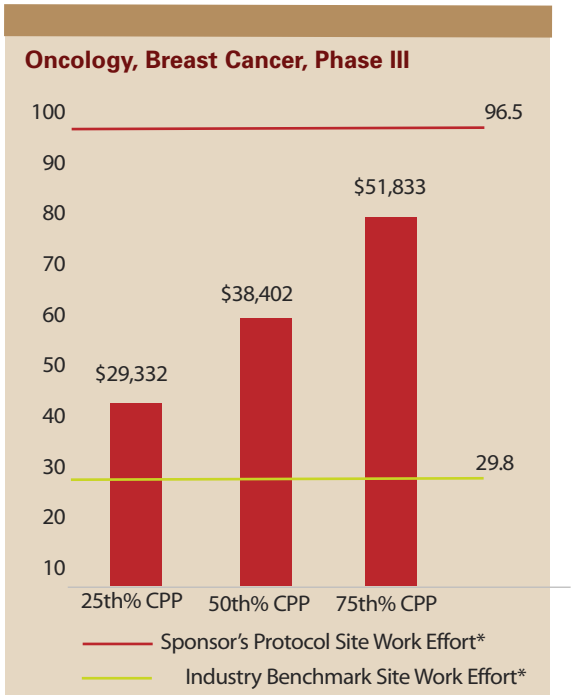
Understanding Protocol Complexity Produces More ACCURATE INVESTIGATOR SITE BUDGETS

Protocol complexity metric, also known as site work effort (SWE), measures the effort required by site staff to implement the procedures in a clinical trial protocol. This metric is based on the amount of time that it takes for the investigative site to perform a procedure called for in the protocol and the skill level required to administer that procedure. The skill level required has been validated by investigators working with the Tufts Center for the Study of Drug Development under a project led by Kenneth A. Getz, MBA, and Director of Sponsored Research Programs. Procedures that are not reimbursable by third parties, such as informed consent or questionnaires, etc., have work effort units (WEUs).

Understanding the complexity of a trial plays a key role in helping sponsors more accurately determine trial budgets and payments to investigator sites, but few have mastered how to apply these metrics to realize cost or efficiency gains. By measuring the relative difficulty for sites to perform the research activities required by the study protocol, and using this data in conjunction with benchmark costs, sponsors can fine-tune budgets to accurately reflect the actual site work required by the study protocol. Without understanding the relative difficulty of their protocol, a sponsor cannot determine the true fair market value payment levels for its study.

Site work effort is a procedure-driven metric. A protocol's SWE score is determined by totaling the SWE per procedure for each time all procedures occur in a protocol. This total, which we call the "protocol complexity score," is then benchmarked against the scores for other studies of the same therapeutic area, phase and indication.



*Benchmark cost data and SWE metric based on the PICAS® database, composed of over one-quarter million negotiated investigator grants and contracts and more than 28,000 final protocols in over 1,400 indications.

A Case Study: Fair Market Value

The case study below illustrates the impact of a highly complex protocol on understanding and determining fair market value rates for site fees. Fair market value rates are presented as benchmarks, per budgetary item (procedures, salaries, etc.), compared with actual negotiated values from studies of the same therapeutic area, phase and indication.

Oncology Breast Cancer Phase III

This study has a SWE metric of 96.5. The average industry benchmark SWE for oncology breast cancer Phase III is 29.8.

The industry benchmark cost levels for the procedures and other costs for this study at the 25th, 50th, and 75th quartile levels are $29,332, $38,402, and $51,833 on a cost per patient (CPP) basis, respectively. This translates into a total CPP range of $22 million to $39 million in this > 750 patient study at the industry low to high cost benchmarks.

The conclusion is both simple and illuminating, pointing to the value of understanding complexity to make smarter site budgeting decisions.

In this example, there is significantly greater site work effort required for each patient participating in the study. The sponsor's study budgeting process must account for the relative difficulty of their protocol in determining the appropriate CPP payment levels to the sites. The significant complexity of this study relative to its peers justifies pricing toward the higher end of the benchmark cost range.

Conversely, if a sponsor's study protocol has a site work effort lower than the industry benchmark for the same therapeutic area, indication and phase, the industry best practice would be to pay at the lower end of the benchmark costs.

Contributed by

FRANK CATTIE, *VP, Trial Planning Solutions (TPS), Medidata Solutions*

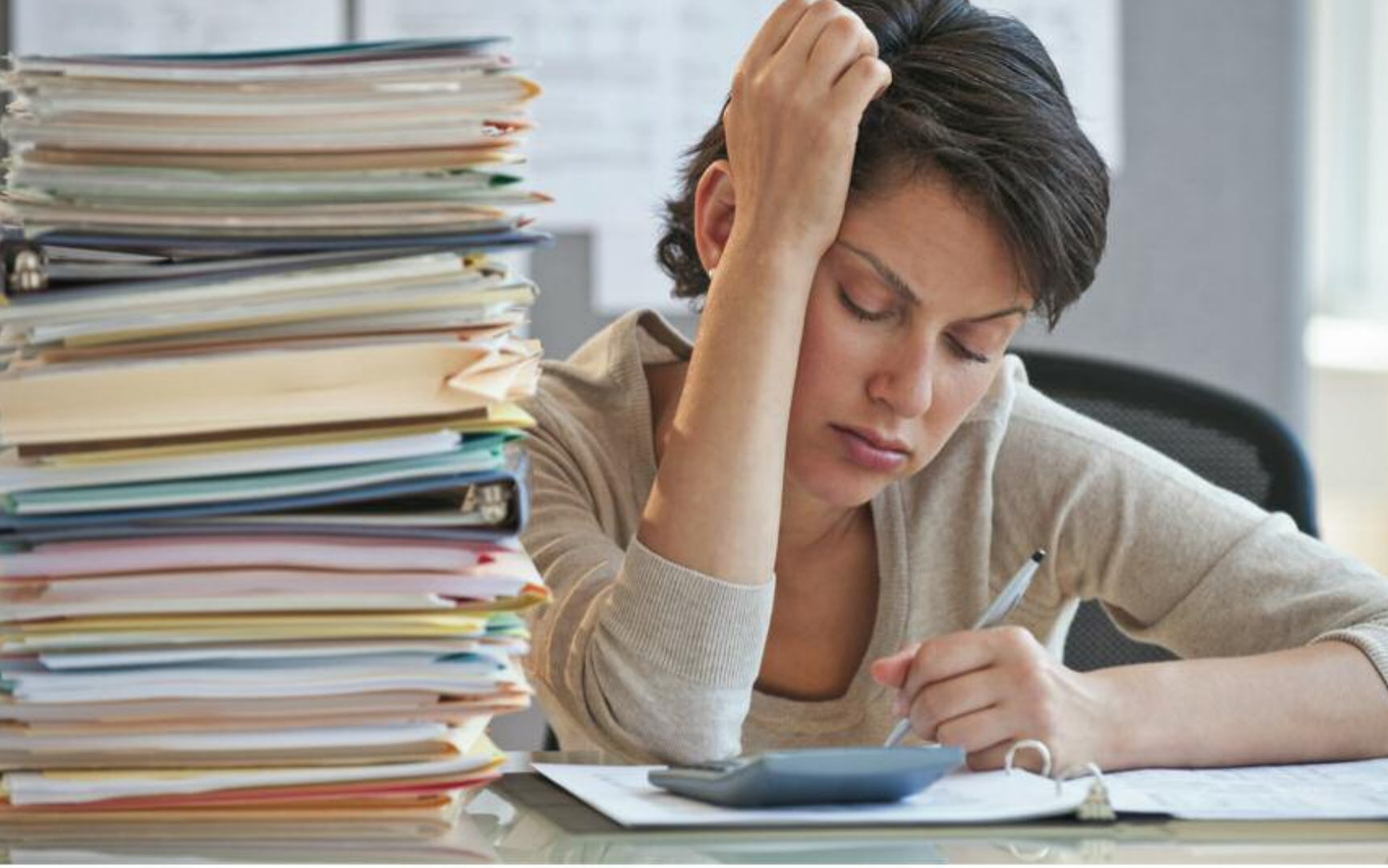
Budget Smartly

Sponsors that do not consider protocol site work effort in determining payment levels for complex studies may effectively under-budget, resulting in extended site negotiations, delayed study start-up, lower site satisfaction, and risk of mid-study budget amendments due to cost.

Alternately, sponsors with relatively simple studies can justify initiating negotiations at the lower end of the spectrum, while still representing fair reimbursement for the services performed and reducing the risk of overpaying healthcare providers. Applying the principles of site work effort to study budgeting is the best way to determine accurate site payments for clinical trials, ensuring fair and appropriate payments while increasing efficiency in negotiating with and paying sites. PV

Medidata Solutions Worldwide *is a global provider of cloud-based clinical development solutions that enhance the efficiency of customers' clinical trials.*

For more information, visit mdsol.com.



Do Your Trial Costs Keep You Up at Night?

Finding every procedure cost for every country in your clinical study takes 24 hours a day and more.

Our industry-leading PICAS® database gives you easy access to over 265,000 grants and 28,000 protocols in nearly 100 countries and regions.

Medidata Grants Manager® works while you sleep.

Email GrantsManager@mdsol.com to learn more.

medidata®
Medidata Solutions Worldwide

www.mdsol.com