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Reducing Drug Development Costs with Protocol Cost Savings Analysis (PCSA)

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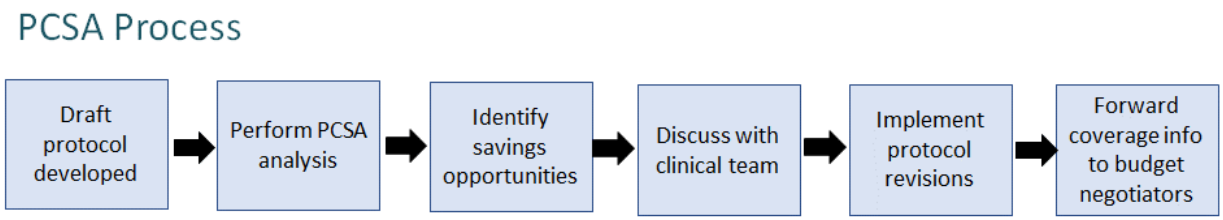
Continuing increases in the cost of clinical research are driving industry-wide efforts to reduce costs, or to at least slow the increases. Many of these efforts are complex, expensive, time-consuming or risky to implement, or can diminish quality or damage the sponsor's (or CROs) relationships with investigational sites. All the while, many sponsors are leaving money on the table that is hiding in plain sight: third-party reimbursements for the costs of tests and procedures that can be deemed "routine care."

Many sites, especially the largest and most sophisticated, perform "Medicare coverage analysis" to identify costs that can be billed to Medicare, Medicaid or other third-party payors, i.e., not the study sponsor. However, since coverage analysis can be time-consuming and tricky — and, if not done properly, might lead to incorrectly billing Medicare — many other sites do not perform this analysis, at least not thoroughly, and simply bill the study sponsor for all costs, assuming the sponsor still wants to swallow the higher costs of conducting the study at that site.

Sponsors can fine tune their protocols so that more tests and procedures qualify for Medicare reimbursement. Even minor modifications in a protocol can yield significant cost savings when applied to all the participants in a study. For example, Medicare might reimburse for a test performed once every four weeks, while a protocol might call for it to be performed twice, three weeks apart. It is highly unlikely that the clinical scientist writing the protocol would have been aware of Medicare's rules. Even if the protocol were adjusted accordingly, many sponsors still would produce budget templates that do not reflect Medicare reimbursement. The study team would probably not learn of the issue until midway through the study start-up process, if they noticed at all. At that point, a protocol amendment would be expensive or entirely impractical.

When coverage analysis is incorporated into the study sponsor's process, it is called "Protocol Cost Savings Analysis (PCSA)," as shown below:



During the study design phase, the sponsor analyzes the protocol to identify any potential savings that might be realized by shifting protocol procedures to better align with Medicare reimbursement rules. For example, minor changes in the timing of tests and procedures might qualify these activities as routine care. The clinical team can then determine whether these changes will affect the desired clinical outcomes for the study. If not, they can be incorporated.

Once the protocol passes FDA review, the sponsor conducts a final PCSA and forwards the analysis to the study team for incorporation into the site study budget grid. Activities that qualify as routine care are so labeled, with the expectation that sites will bill third-party payors accordingly.

Since it is the site that requests reimbursement from third-party payors, the site has final responsibility for determining which study activities qualify. At minimum, the sponsor's determination gives the site a head start on its coverage analysis, and it might point out tricky elements, e.g., regional differences in Medicare reimbursement. A PCSA also gives the sponsor a basis for negotiating charges that the site might want to bill to the sponsor instead of Medicare.

Once a budget has been finalized with a site, the final step is to align the study budget and payors with the clinical trial agreement (CTA) and informed consent form (ICF), to ensure consistency in representations made to the study participant. Any lack in consistency can lead to troublesome, time-consuming and expensive disputes down the road, to say nothing of potential amendments to the CTA or ICF.

PCSA Oncology Case Studies

The use of a PCSA makes the most sense for studies in therapeutic areas with routine care that involves expensive tests and procedures. Examples include cardiology and, especially, oncology. Oncology and cardiology are ideal therapeutic areas to focus on because protocol-required tests and procedures often align closely with national treatment guidelines, Medicare rules and regulations, and the care a patient would receive absent a study. For example, oncology patients typically have imaging performed on a regular schedule, regardless of participation in a trial. A cardiology patient might have follow-up echocardiograms performed annually after certain procedures.

The financial benefit from performing a PCSA can be significant. For example, a recent PCSA on a 400-participant oncology study identified more than $4 million in potential cost savings. A second, 230-participant oncology study saved $2 million, not counting 12 conditional procedures per participant.

Conclusion

PCSA is an easy, straightforward way for sponsors, sites and CROs to reduce costs, save time, and avoid amendments to study documents.

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