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A Win-Win Solution to the Study Budget Problem

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Study budgets are a point of contention, to put it mildly, between sponsors and sites. Although medical activities, such as physical exams and procedures, are often well-compensated, most study activities are not even in the budget. These study activities are the infamous "hidden costs," and they comprise 75 to 90 percent of the hours consumed by a typical study. It's hard to run a profitable business when 75 to 90 percent of your direct costs (before overhead!) are unbillable.

On the one hand, sites see razor-slim margins and feel powerless to negotiate larger budgets. On the other hand, sponsors see a continuing influx of new industry investigators that are happy to accept almost any budget, often without even reading the clinical trial agreement. Sites see the pharmaceutical industry's billions of dollars of profits and costly marketing practices. The pharmaceutical industry sees continuing erosion in its profitability due to patent expirations, drug re-importation, and problematic research and development (R&D) pipelines.

Understanding Study Costs

CRT codes complement the Common Procedural Terminology (CPT) codes that physicians use for billing. A few CRT codes cover medical activities, such as physical exams, that surprisingly do not have CPT codes. Other codes cover study visit research activities, such as reviewing eligibility criteria and obtaining informed consent. Most CRT codes, however, cover the multitude of activities that occur outside study visits. Most of these activities are unbillable hidden costs. Table 1 presents examples of CRT codes.

Why classify and track activities that the sponsor is never going to pay for anyway? There are actually some very good reasons:

- Sites need to understand their labor costs to determine their profitability. In a business with shared facilities and multiple sources of revenue, it is seldom obvious which lines of business are generating the profits.
- Sites have friends as sponsors and CROs who could use these data when determining study budgets.
- Sites could benchmark their costs against industry norms and cost leaders.
- Sites could streamline wasteful business processes both internally and with their sponsors. Industry-wide collaboration would have the broadest impact.

This last reason is the most important. If sites were going to solve the budget negotiation problem, they probably would have done it already. (Maybe some have, but they're not admitting it.) Clinical research is not the first industry to discover that customers resist price increases.

The next steps are to realize that increasing productivity is the best way to improve profit margins and that cooperation between suppliers and customers is the best way to improve productivity.

Unfortunately, from the sponsor's perspective, there is little or no blood left to squeeze from the "investigator stone." There may even be a backlash brewing. Sites don't want to criticize their customers, but many are wary about their long-term viability. There is, of course, an inevitable movement of trials to low-cost countries, but probably everyone agrees that it is necessary to preserve a healthy clinical research industry in developed countries.

Therefore, the best opportunity is the win-win solution of increasing industry productivity. Higher productivity translates into lower costs and higher profits, even with lower study budgets. Lower costs make more studies feasible, providing plenty of work to maintain full employment. In fact, higher productivity usually translates into increasing employment, faster product delivery, and higher quality products—witness Japan's postwar automotive industry.

Can We Improve Productivity?

There is plenty of room to improve productivity *and* quality *and* speed. How many other industries, like clinical research, need rowboats to navigate their oceans of paper? Let's consider just one technology that is ready to be implemented today: eSource documents. eSource documents address a fundamental flaw of eCRFs: They provide a benefit to all parties. Asking a study coordinator to use an eCRF is like asking

the runners in a footrace to carry a computer on their backs. There are costs, but there are no benefits to the study coordinator. eSource documents, on the other hand, eliminate CRFs entirely and almost all the manual transcription. They also eliminate the baffling requirement that every site create its own source documents. There are huge benefits to the sponsors as well, which the author will leave as an exercise for the reader.

An eSource document with the following specifications could be built today from off-the-shelf technology:

- wireless tablet computer with stylus data entry and character recognition
- standard eCRF functionality
- integrated instructions and illustrations
- handwriting and voice capture for progress notes with real-time offshore transcription
- integration with sponsor's database for sophisticated real-time data validation (say goodbye to most data queries)
- real-time access to the informed consent form, protocol, investigator's brochure, frequently asked questions, etc.
- real-time chat with medical monitor

But, we need paper source documents, right? Well, what function do they serve? It makes perfect sense for data extracted from medical charts to be traceable back to their origins, but why enter fresh data into purpose-built source documents just so it can be copied into a CRF/eCRF? When you write a letter, do you handwrite it on paper first and then transcribe it into your computer?

But if technology is too scary, there is a nontechnological way to substantially improve source documents: Script them. Using current source documents is like singing a song with the words on one sheet (the source document) and the notes on another (the protocol). With the protocol instructions included in a "scripted source document," we save time and reduce errors by integrating step-by-step protocol instructions with the data capture fields.

Other productivity opportunities need to be researched to identify the best practices. Let's look at a process that has been performed millions of time: informed consent. Given that we are in the clinical *research* industry, has anyone conducted scientific research on the most efficient and highest-quality process? Does anyone really know for sure

- What information should be communicated to the candidate in the initial phone contact?
- When, if ever, is it appropriate to mail informed consent forms before the initial visit?
- Is it better to verbally review the informed consent form before or after the candidate reads it?

Efficiency can be measured in hours per enrolled (and retained) subject. Quality can be measured with comprehension quizzes. With widespread adoption of best practices (whatever they are), the industry's overall informed consent productivity and quality can be improved substantially.

Table 1. Sample CRT Codes

Pre-Study Activities		**Regulatory Activities**	
R1014.	Pre-study Visit, Prepare for and Attend	R1511.	Central IRB, Prepare for and Submit and Track Application Renewal
R1020.	Investigator Meeting, Investigator Attend	R1532.	Recruiting Materials, Obtain Sponsor and IRB Approval
R1040.	Site Initiation Visit, Prepare and Attend	R1550.	IND Safety Reports, Process
R1071.	Source Document Forms, Prepare from CRFs	R1590.	Closeout Report, Complete
Recruiting & Prescreening Activities		**Study Record Activities**	
R1110.	Recruiting Materials, Create	R1600.	Study Records, Archive
R1120.	Referral Sources, Identify, Recruit and Manage	R1610.	Study Records, Store
R1140.	Telephone Inquiries, Answer	R1620.	Study Records, Retrieve
R1141.	Prescreen Potential Subjects, Telephone	R1630.	Study Records, Destroy
Study Visit Activities		**Sponsor-Related Activities**	
R1210.	Informed Consent, Obtain	R1700.	Site Monitor Visit, Manage
R1212.	Obtain signed medical information release form	R1710.	Sponsor Audit, Manage
R1214.	Inclusion/Exclusion Criteria, Interview for	R1740.	Protocol Clarification, Obtain
R1229.	Randomize	R1741.	Change to Study CRF, Protocol, etc., Manage
Between-Visit Activities		**Assessment Activities**	
R1320.	Third-party Procedures and Tests, Manage	R1800	ADCS-ADL
R1321.	Lab Results, Review	R1801.	CBQ
R1326.	Primary Care Physician, Keep Informed	R1802.	CDAI
R1353.	Monitor Compliance	R1803.	CIBIC-Plus
Adverse Event Activities		**Other Activities**	
R1400.	Adverse Events, Monitor and Evaluate	R1903.	Receive Study Materials
R1410.	Adverse Event, Assess and Manage	R1930.	Review and Manage Protocol Amendment
R1420.	Serious Adverse Event, Assess, Report & Manage	R1932.	Reconsent Subjects
		R1940.	Clinical Supplies, Obtain Missing Item(s)

Call to Action

Problems seldom solve themselves. Someone has to take the initiative to break away from the status quo. If the study budget problem is going to be solved before it irreparably damages the industry, we had best start working together now.

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