“Spurring Collaboration - Building & Negotiating a Study Budget”

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Disclaimer!

- I am neither an accountant or lawyer, and therefore am not providing legal or financial advice, approach your own advisors for such
- I am not suggesting a price to charge for any services, I am only providing a formula for you to determine what your costs may be
- I am not guaranteeing results for favorable outcomes of audits or financial gains

Overview

- The Cost of Doing Business
- Line Items
- Closing Costs
- Post-Closeout Costs
- Budgeting
- Cash Flow
- Payment Language
- Negotiating Summary

The Cost of Doing Business

- The cost of doing business is overhead.
- These are costs that cannot be identified with a specific clinical trial but are needed for the general administration of the organization.

Cost of Doing Business, cont'd:

Not mentioned in the previous examples:

- *Project-specific* audits
- *Project-specific* meetings, phone conferences
- *Project-specific* training

**if there is no project, there is no "cost of doing business" that only comes about because of that project.*

General Study Costs / Line Items

Line Items

- FDA Audit (if warning letter issued)
  - Daily rate * number of days
- Sponsor Audit
  - Daily rate * number of days
- Electronic Training
  - Hourly rate for Coordinators, Investigators

Line Items (cont'd)

- Continuing Review
  - Coordinator completion, PI review, submit, file
- IND Safety Reporting
  - PI review, filing
- Protocol Amendment
  - PI and Coordinator review, file

Line Items (cont'd)

- Medical Record Copying
  - Assign CRA a copier code
- Phone Meetings, Webinars
  - Hourly rate for each participant
- Reconsenting
  - Hourly rate or flat fee

Line Items (cont'd)

- Unscheduled Subject Visits
  - Hourly rate, or flat fee
- SAE Reporting
  - Hard to quantify, some sponsors pay based on severity, others pay flat fee
- Additional Monitoring
  - First you had one monitor, now you have 2 plus trainee for 3 days per month

Sample Line Items Checklist

Audit - FDA per day
Audit - other - per day
Document destruction
Documents retrieval & return
Electronic training - PI - per hour
Electronic training - SC - per hour
Continuing review
IND safety reporting
Protocol Amendments
Phone meeting - PI - per hour
Phone meeting - SC - per hour
Re consenting - per subject
Return of unused study supplies
Serious adverse event reporting
Unscheduled subject visit
Visit - close out - PI & SC
Visits - CRA & trainee per additional day
Visits - CRA per additional day

Budget & contract preparation
Investigator meeting - PI or Sub I
Investigator meeting - SC
IRB - preparation & initial submission
IRB - preparation & submission for close out
Lab set up
Legal review
Long term document storage
Pharmacy close out
Pharmacy monthly inventory ($100/mo x 12 mo)
Pharmacy set up
Pre-screening for eligible volunteers
Site initiation visit
Source document preparation
Study specific staff education

Contract Items / Language

- Screen Failures
- Long-term document storage
- Payment schedules

Change of Work / Change Orders

- Standard Change Order Language
  - (a) The Contracting Officer may at any time, by written order, and without notice to the sureties, if any, make changes within the general scope of this contract in any one or more of the following:
  - (1) Description of services to be performed.
  - (2) Time of performance (*i.e.,* hours of the day, days of the week, etc.).
  - (3) Place of performance of the services.

http://www.arnet.gov/far/current/html/52_241_244.html#wp1128962

Change of Work / Change Orders

- Standard Change Order Language

  "…Failure of the parties to agree to an adjustment shall not excuse the (Site) from proceeding with the contract as changed, provided that the (Sponsor) promptly and duly makes provisional adjustments in payment or time for performance as may be reasonable. By proceeding with the work, the (Site) shall not be deemed to have prejudiced any claim for additional compensation, or an extension of time for completion.

http://www.rules.utah.gov/publicat/code/r033/r033-006.htm

Change of Work / Change Orders

- Having a Change Order clause in a contract is a standard business procedure
- Changes to design of a trial affect site's resources
- Small changes add up
- 63% of Investigators never do another trial

Closing Costs

- Close-out Visit
  - Hourly rate or flat fee
- Return of Unused Study Supplies
  - Hourly rate or flat fee

Post Close-out Costs

- Long-Term Document Storage
  - Read your agreement with the facility:
    - Monthly charge per cubic foot (assume this will increase over time!)
    - Fee to enter documents into inventory
    - Fee to remove documents from inventory
    - Fee for destruction (fire vs. shredding)
- Document Retrieval
  - Charge to remove boxes, deliver, and return
  - Don’t forget to charge overhead!

What Do The Regulations Say About Storage?

CFR: Sec. 312.62 Investigator recordkeeping and record retention.

- (c) *Record retention.* An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

What Do The Regulations Say?

ICH:

4.9.5 Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained (see section 5.5.12).

Post Close-out Costs

<u>These Scenarios Can Change Your Document Storage Costs</u>

- Over-enrollment
- Long study
- Excessive safety reports
- Inflation
- Retrieving files
- Sponsor stores documents

*If you have more documents at the end of the trial than you initially accounted for, prepare a detailed explanation of why you need an increase (see Excel sheet)

Sample Startup Packet

Items to include:

- All startup, line items, and closeout fees with justification
- Justification for all language edits
- Rationale for overhead
- On letterhead
- Signed

Important

The Per-subject Budget and the Study Budget

are two different things.

- The Per-subject budget covers the activity related to the subject.
- The Study Budget covers the entire trial: upfront, screening, monitoring, etc.

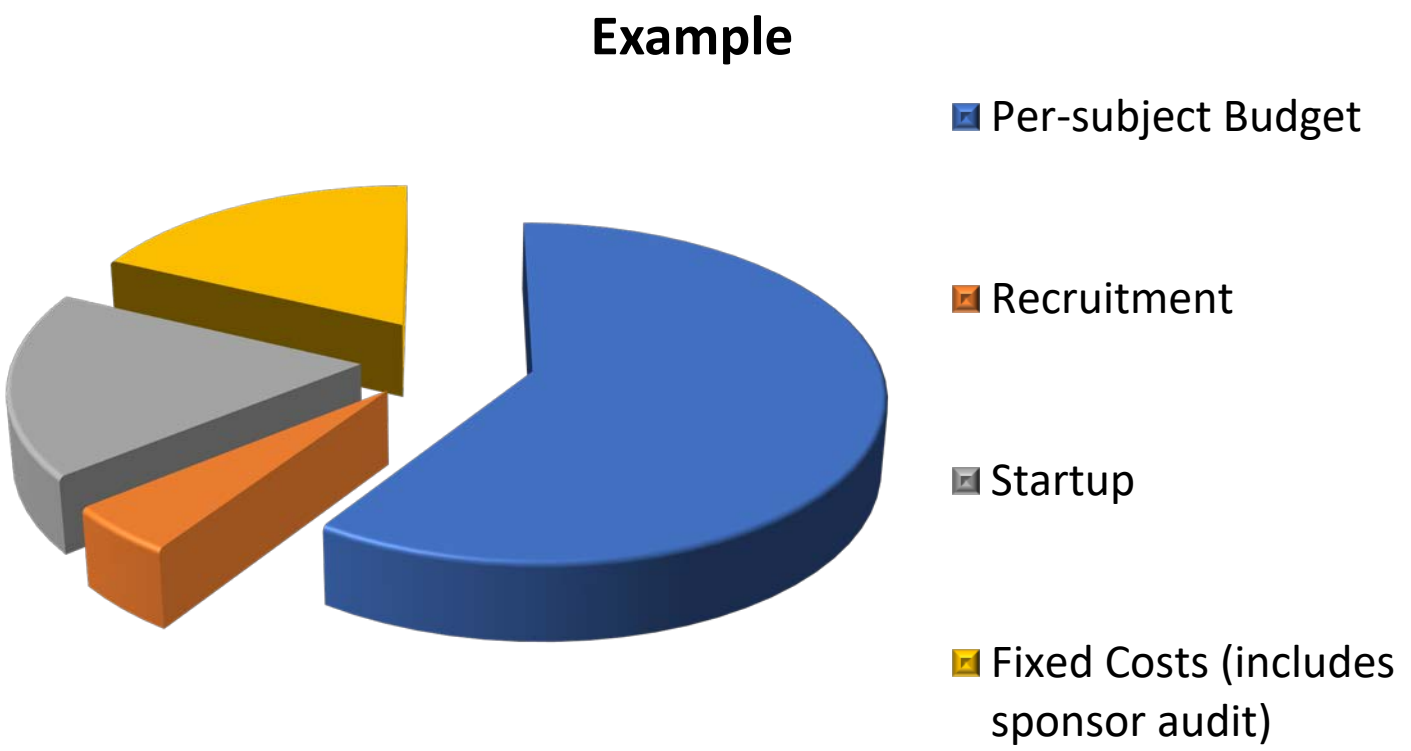
Study Budgets

- The Study budget should, when all items are factored in, cover the *cost+OH+profit* for getting the site up, meeting the enrollment goal, and closing the trial. If the startup is not paid as a line-item, for example, then the per-patient budget must be raised to cover the startup costs.

Study Budgets

- If items that can vary are not covered by line items (SAE's, safety reports, phone conferences, protocol amendments) then an adequate number of these must be built into the per-patient budget and if the number is exceeded then it's time to go back to the sponsor for egregious abuse of site resources. Chances are you will not be alone making this call.

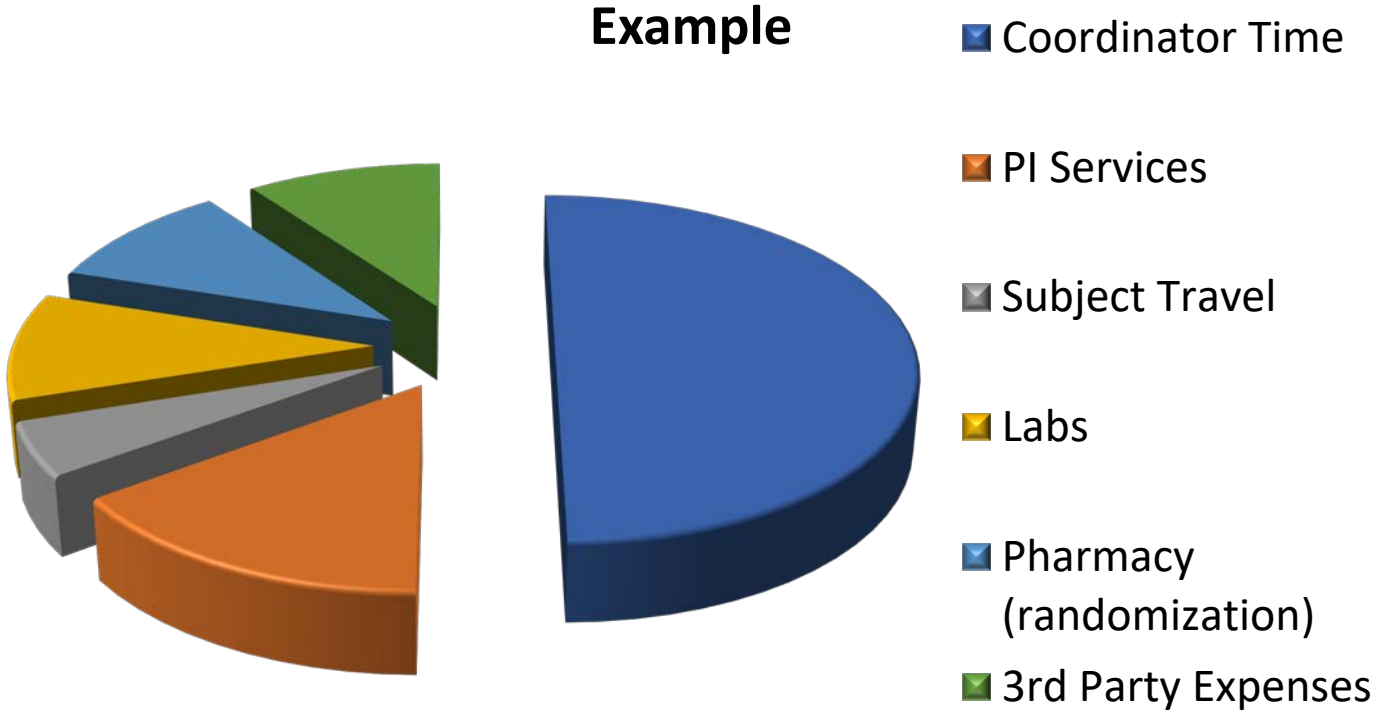
The Study Budget



Per-Subject Budget

- What it should cover
  - Getting a subject through the trial
  - Subject-specific expenses
  - Subject-specific labor
  - Overhead
  - Profit
  - It may have to cover more if you cannot get line items covered outside of the per-patient budget

The Per-Subject Budget



Per-Subject Budgets

- What is not specifically covered
  - Monitoring
  - Training
  - IRB renewals
  - Audits
  - Close-out visit
  - SAE's (sometimes there is a line-item for that)
  - Screening activities
  - Return of study materials to sponsor

Per-Subject Budgets

- Ways to calculate the per-subject budget
  - By time
  - By element
  - Combination
- Ways sponsors pay
  - By element
  - Lump sum

Case Study

- Assumptions:
  - –Coordinator billed at $200/hr
  - –Investigator billed at $500/hr
  - –Inpatient
  - –4 visits, 2 in, 2 follow up
  - –Goal of 6
  - –12 monitor visits expected
  - –Sponsor audit

Billing Out Your Coordinator

2080 hours in a work year

less 48 holiday hours

less 80 vacation hours

less 40 sick hours

less 80 hours spent at PI meetings (2 days/PI meeting x 5 meetings)

equals 1832 "gross" billable hours

80 % proficient =

1465 BILLABLE HOURS

For the next examples, I will have a coordinator bring in $294,000.

Billing Out Your Coordinator

Solution #1: Working Backward From the Goal

If I start with 2080 hours in a year (40 hrs x 52 weeks), and back out 120 hrs PTO, 48 hrs holidays, 80 hrs at PI meetings (2 days at 5 meetings) then that leaves 1832 hours left for them to recover the $294,000, which would be a billable rate of $160/hr (rounded) *assuming that every hour they're working, they're engaged in billable activity*.

If they are only spending 80% of their time doing study-specific billable activity, that's 1466 hours or a billable rate of $200/hr.

Billing Out Your Coordinator

Solution #2: Working Toward the Goal

The other approach to the problem is to bill the coordinator at, for example, 3x their hourly pay rate (typical for a service industry) and what the coordinator must do is bill $294,000 no matter how many hours it takes to do so. If they spend 80% of their time on billable activity at a rate of $150 hr, that's $294,000/$150 = 1960 hours, or 80% of 2450 hours. The hours of PTO, holidays, etc, are 8-hour "days", that add up to 248 hours/31 days, leaving 260 work days in a year less 31 days = 229 days to work 2450 hours, or nearly 11 hours per day.

Billing Out Your Coordinator

How did I arrive at the 3x hourly rate of $150? I divided a sample yearly salary of $72,000 ($60,000 + 20% benefits) by the 1466-hour figure from Solution #1 and multiplied by three, which is done to cover overhead and profit. Those numbers would vary by each site's pay rate, overhead, and profit.

If a site is budgeting a trial and not building overhead and profit into the coordinator's rate or recovering it in some other fashion, they are simply passing the coordinator's salary through to the sponsor.

Billable Rates

- Solution #3
  - Salary $50,000 + 20% benefits package = $60,000
  - 1832 hours to break even on salary is $32.75/hr
  - Coordinators are only paid to do half of what they do, so I have to double the rate to $65.50
  - 3x is $196.50, or about $200/hr

Item	Time	Price
PI Meeting / CRC	16	$3200
PI Meeting / PI	8	$4000
IRB submit / CRC	4	$800
IRB submit / PI	1	$500
Initiation / CRC	6	$1200
Initiation / PI	1	$500
Inservicing	3	$600
Source Docs	6	$1200
Training / CRC	2	$400
Training / PI	2	$1000
Screening	20	$4000
Lab Startup		$500
Pharmacy Startup		$500
Total		$18,400

“Fixed” Activity

Item	#	Hours	Price
Monitoring Visits	12	3	$7200
Sponsor Audit	4	8	$6400
IRB Renewals	1	2	$400
Close Out	1	6	$1200
Document Storage			$750
Total			$15,950

Per-Subject Activity

Visit	1	2	3	4	Total
Day	1	2	30	60	
Physical	$150			$150	$300
PI Oversight	$200	$200	$200	$200	$800
Coordinator	2	2	2	2	$1600
Labs	$130	$65	$130	$130	$455
Subject Travel			$40	$40	$80
Total					$3235

Summary

Item	Total
Startup Activity	$18,400
Per-Subject Activity	$3235 x 6 = $19,410
Fixed Activity	$15,950
Total	$53,760

The per-subject budget that will cover this project is $53,760 / 6 = $8960.

Also, when you add up all the coordinator hours (181) and divide by the number of subjects, you get 30 hours per subject.

What If…

Enrollment Goal	6
Coordinator Name:	CRC
Cost per Hour	$135.00
Investigator Cost per Hour	$0.00

Total Per Subject cost	$2,715.00
Total Cost	$2,715.00
Per Subject Reimbursement:	$6,000.00
(Per Patient to Sponsor:	$9,000.00
original	5000
% diference	20%
Per Subject Profit	$3,285.00
Total Study Cost	
Upfront Cost	$8,695.00
If Enrollment Goal Met:	$16,290.00
non - patient fixed costs	$11,010.00
Total	$35,995.00
Sponsor Grant	36,000.00
start-up	0.00
Profit/Loss	**5.00**

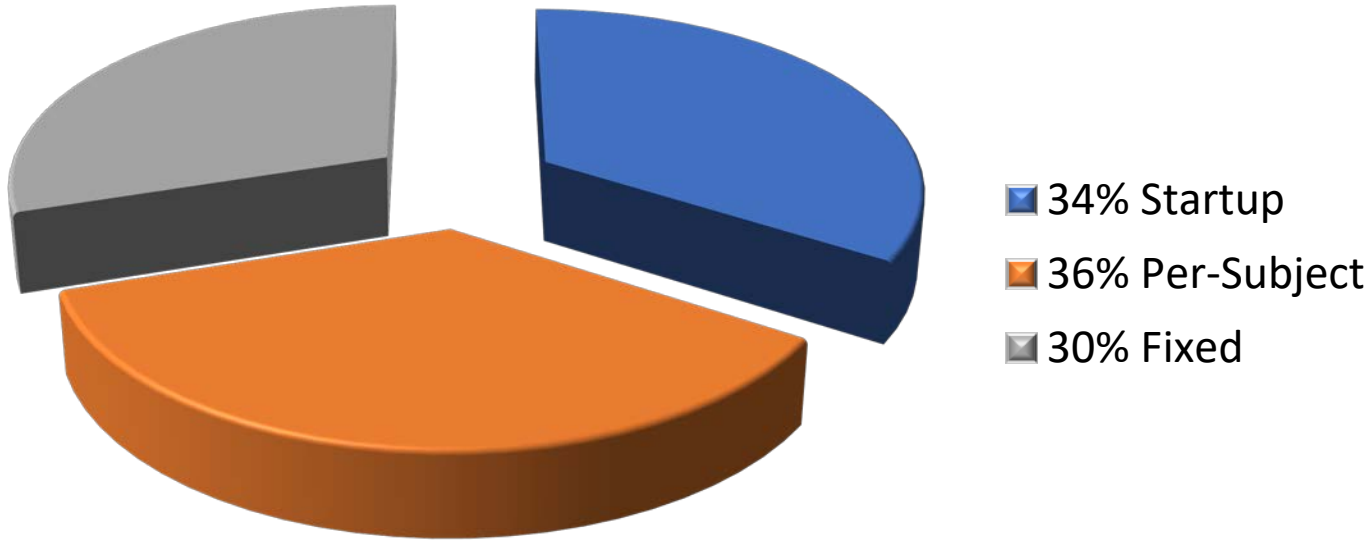
What if…

Your coordinator's cost per hour is $50?

Enrollment Goal	2
Coordinator Name:	CRC
Cost per Hour	$50.00
Investigator Cost per Hour	$0.00
Total Study Cost	
Upfront Cost	$3,850.00
If Enrollment Goal Met:	$4,070.00
non - patient fixed costs	$4,550.00
Total	$12,470.00
Sponsor Grant	12,000.00
start-up	0.00
Profit/Loss	**(470.00)**

Enrollment Goal	3
Coordinator Name:	CRC
Cost per Hour	$50.00
Investigator Cost per Hour	$0.00
Total Study Cost	
Upfront Cost	$3,850.00
If Enrollment Goal Met:	$6,105.00
non - patient fixed costs	$4,550.00
Total	$14,505.00
Sponsor Grant	18,000.00
start-up	0.00
Profit/Loss	**3,495.00**

"We don't pay for that."



Your only concession is the coordinator’s billable rate.

How much work can a coordinator handle?

How Many Trials Can a SC Coordinate?

	Academic	Hospital	Private practice	Stand-alone
average study coordinators	4	9	4	5
average number of new studies	30	26	11	17
2010 number of studies/SC	8	3	3	3
2009 # of studies/SC	.66	1	5	4

Site Solutions Summit Site Survey 2011

Coordinator Productivity

$250,000.00	/year/coordinator
1.00	coordinators needed
$50,000.00	average coordinator salary + benefits
$500.00	Average visit amount:
10	Average visits/study/year
10	Average enrollment goal:
$5,000.00	average per patient amount
100	visits/study
500	visits required to make goal
2	visits/day needed to make goal
2	visits/day/coordinator
5.00	studies needed to make goal
50	patients needed per year
50.00	patients needed/year/coordinator
4.17	patients needed per month
4.17	patients needed/month/coordinator
1.00	patients needed per week
1.00	new patients/week/coordinator

Coordinator Productivity

30	Hours to get patient through average trial
1500	total hours needed per coordinator to fulfill enrollment goal
2080	total hours of coordinator time available/year
80.0	hours out for PI meetings (studies/coordinators * 2 days)
120	hours pto
56	hours holidays
256	total hours subtracted from available working hours
1824	total hours
80%	efficiency
1459	total coordinator hours available to accomplish goal
(41)	hours difference
49	patients can be enrolled with available time

Cash Flow

Cash Flow Pressures

- Payment Terms – Net Days
  - Staff Wages: 0
  - 3rd Party: 30
  - IRB: 30
  - Advertising: 30
  - Rent: 30
  - Utilities: 30
  - Subject Reimbursement: 0

Cash Flow

Inpatient cardiac surgery study

- Enrollment goal is 20
- Will enroll for 6 months, but they know they will fill this one quickly, about 4 subjects per week
- Quarterly payments (usually arrive 6 weeks after the quarter)
- 10% withholding for completion of 6-month follow-up and resolution of all queries
- There is a 28-day follow-up as well

Cash Flow

Visit amounts:

- Fee for completion of Assessment 1 and Assessment 2: $ 1925 USD (55%)
- Fee for completion of Assessments 3, 4, and 5* (28-day follow-up): $ 1225 USD (35%)
- Fee for completion of Assessment 6 (6-month follow-up) and satisfactory resolution of all queries: $ 350 USD (10%)
- Total: $ 3500 USD (100%)

*Assessment 3 is ICU discharge and Assessment 4 is hospital discharge. Note that sponsor is tying the Day 28 follow-up to Visits 3 and 4. If this site is able to change to monthly terms, they should separate Visit 5 from 3 and 4.

Setting up the Analyses

Things to Consider:

- Enrollment goal
- Enrollment period (i.e. 6 months)
- Enrollment rate (i.e. 1 subject / month, or perhaps a big lump and the start and then trickling in)
- When payment will *actually* arrive
- The withholding percentage
- When final payment will arrive (read the terms carefully)

Setting up the Analysis

1) Map out the months/weeks of how long the study will last, from first subject enrolled until final payment is received
2) Determine enrollment rate – will you enroll one per month, every 6 weeks, every day?
3) Plot enrollment using the contracted amounts for the visits (This is not a profitability analysis.)
4) Total the amounts
5) Plot the payments. Be realistic – when will that "quarterly payment" actually arrive? What about the final payment?
6) Total the difference between site outlay and payment receipts.
7) Highlight the difference and use the Excel graphing function to plot a graph.

The First 8 Weeks

Subject		W 1	W 2	W 3	W 4	W 5	W 6	W 7	W 8	W 9
1		1925			1225					
2		1925			1225					
3		1925			1225					
4		1925			1225					
5			1925			1225				
6			1925			1225				
7			1925			1225				
8			1925			1225				
9				1925			1225			
10				1925			1225			
11				1925			1225			
12				1925			1225			
13					1925			1225		
14					1925			1225		
15					1925			1225		
16					1925			1225		
17						1925			1225	
18						1925			1225	
19						1925			1225	
20						1925			1225	
Totals	0	-7700	-7700	-7700	-12600	-12600	-4900	-4900	-4900	0
Payments										
Cum. Totals	0	-7700	-15400	-23100	-35700	-48300	-53200	-58100	-63000	-63000

The Follow-up Visits

W 24	W 25	W 26	W 27	W 28	W 29	W 30	W 31
350							
350							
350							
350							
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		350					
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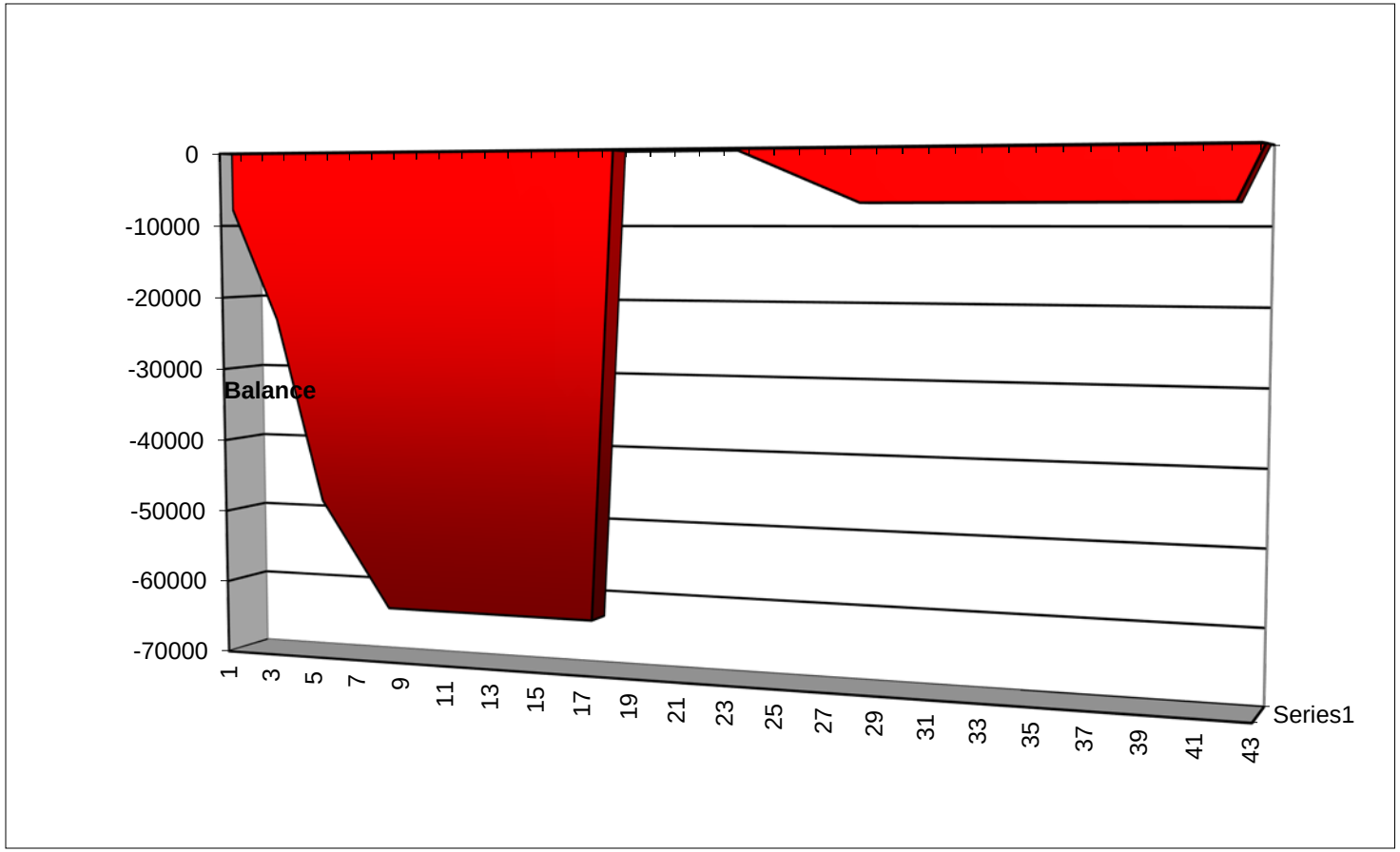
				350			
-1400	-1400	-1400	-1400	-1400	0	0	0
-1400	-2800	-4200	-5600	-7000	-7000	-7000	-7000

Graphic Timeline



Cash Flow

What could ease the cash flow burden at the site?

- Monthly payments, paying 95% of the per subject amount of randomized subjects
- 25% upfront (5 complete subjects)
- 5% withholding (20*$3500*.05= $3500, which is incentive enough to resolve all queries)
- This even puts the site in a state of being ahead for a while

The First 8 Weeks

Subject		W 1	W 2	W 3	W 4	W 5	W 6	W 7	W 8	W 9	W 10
1		1925			1225						
2		1925			1225						
3		1925			1225						
4		1925			1225						
5			1925			1225					
6			1925			1225					
7			1925			1225					
8			1925			1225					
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13					1925			1225			
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15					1925			1225			
16					1925			1225			
17						1925			1225		
18						1925			1225		
19						1925			1225		
20						1925			1225		
Totals	0	-7700	-7700	-7700	-12600	-12600	-4900	-4900	-4900	0	0
Payments		17500					36575				13300
Cum. Totals	0	9800	2100	-5600	-18200	-30800	875	-4025	-8925	-8925	4375

The Follow-up Visits

W 24	W 25	W 26	W 27	W 28	W 29	W 30	W 31	W 32	W 33	W 34	W 35	W 36
350												
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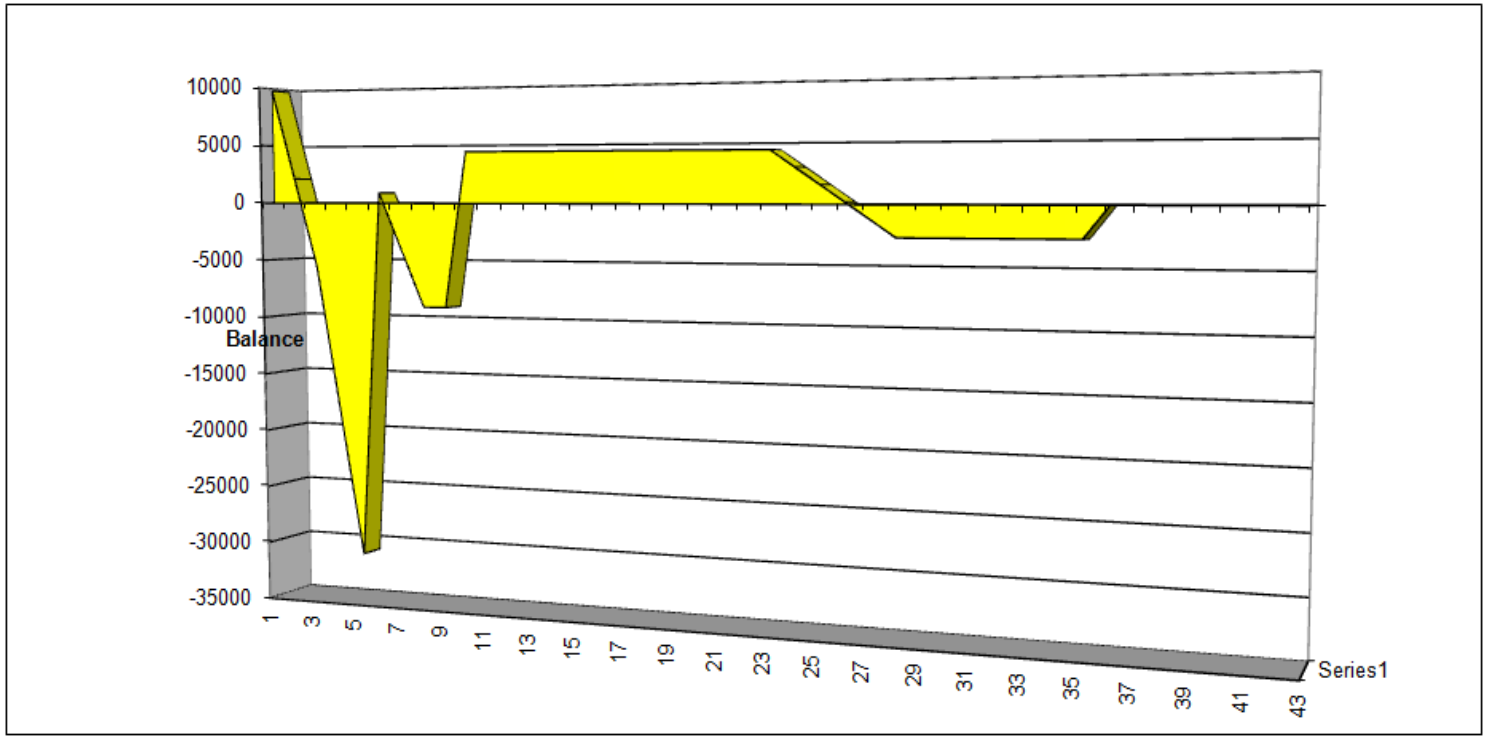
-1400	-1400	-1400	-1400	-1400	0	0	0	0	0	0	0	0
												2625
2975	1575	175	-1225	-2625	-2625	-2625	-2625	-2625	-2625	-2625	-2625	0

Graphic Timeline



Conclusions

- Sites perform better when they can focus on enrollment rather than cash flow
- Slow and late payments can lead to other issues at sites:
  - Advertisers demanding payment upfront
  - Increased uses of lines of credit
  - Disgruntled 3rd party providers
  - Subject safety (where do they go when the site closes?)
  - Data integrity
  - Study delays
  - Fraud

Society for Clinical Research Sites, Inc. is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

Conclusions

Sponsors will have better study results if they have lower site turnover.

Experienced sites:

- are more likely to be your top performers
- deliver cleaner data
- are less likely to need to return startup money
- present the opportunity for Master Agreements
- view this as a business and not a side project
- keep study documents as per regulatory expectations
- need less training
- are committed business partners

Payment Terms

An initial advance payment in the amount of US $XXX.XX (one completed patient) will be made to INVESTIGATOR. (When will this payment be made?) Additional STUDY payment will commence when US $XXX.XX has been earned based upon patient enrollment and receipt of acceptably completed case report forms at CRO.

Payment Terms

e. If any overpayment occurs, CRO or the SPONSOR shall be reimbursed the overpaid amount as instructed by CRO. Reimbursement shall be paid within 30 days of notification by CRO.

g. In the event the STUDY is terminated early, total payments due shall be calculated as follows:

i.) Amounts payable for actual procedures performed and CRF's completed as defined in Section 4c and as yet unpaid, and

ii.) Actual procedures performed and CRF's completed from the date of termination until the STUDY closure as instructed by CRO and/or SPONSOR.

iii.) Any non-cancelable expenses incurred by the INVESTIGATOR…

Screen Failures

If a patient fails the screening process, the INVESTIGATOR will receive compensation in the amount of a Visit 1 rate, if the complete screening procedure (Visit 1 and Visit 2) was performed or if a patient fails the screening process due to laboratory values. A patient who fails the screening process already at Visit 1 will not be remunerated. The INVESTIGATOR will receive compensation for a number of screening failures that equals or is less than 50% of the number of patients randomised according to protocol. E.g.: If 8 patients are randomised according to protocol, a maximum of 4 screening failures will be compensated.

Payment Terms

"…The last payment for the study will be processed once all data queries have been resolved and all required study documents have been received at CRO for all sites".

"INVESTIGATOR acknowledges and agrees that they have no recourse against CRO for monies owed under this Agreement that have not been previously provided to CRO by Sponsor." (see next slide)

Payment Terms

Your contract may also say:

"Sponsor will provide funding to CRO to conduct the Study. CRO shall make payment to Institution upon its receipt of funds from Sponsor. In the event of non-payment by CRO, Institution/ Principal Investigator's exclusive cause of action for non-payment shall be against CRO and not Sponsor; provided, however, CRO assumes no financial liability in the event funds are not made available to CRO by Sponsor."

Payment Terms

How to fix this:

"CRO will pay (you) in accordance with the amounts and schedule set forth in the Payment Schedule, attached hereto as Attachment A. BECAUSE CRO IS UNABLE TO PROMISE TO PAY (you) UNTIL SUCH TIME AS IT IS PAID, SPONSOR HAS JOINED THIS AGREEMENT AS GUARANTOR, AND WILL ASSURE PAYMENT IS RECEIVED BY (you), NOTWITHSTANDING ANY FAILURE BY CRO TO MAKE ANY PAYMENT WHEN DUE."

Sample Generic Change Order Language

If the Protocol is amended or Sponsor issues written or verbal instructions (which are later reduced to writing) that increase the cost or time of performance of the Clinical Trial, an amendment will be generated to specifically provide for payment of the increase in cost and for an extension of time, if such extension is required.

Audits

…Randomly occurring Audits or FDA inspections will be conducted at the expense of the (Sponsor/CRO) as outlined in the (budget reference). In the event of a "for-cause" Audit or FDA inspection in which no warning letter is issued, (Sponsor/CRO) shall also reimburse (payee) at the rate outlined in the (budget reference).

Sample Language I

"The site will be paid a non-refundable administrative start-up fee of $ XXXX.XX for services incurred but not limited to:

Principal investigator meeting; regulatory and IRB preparation and submission; budget & contract negotiation; source document development; staff education; pre-screening for eligible subjects; and site initiation.

Payment will be made with 15 days of the execution of this contract."

Compensation

<u>Contact for payment matters</u> will be:

(name address phone fax email)

Compensation

…Unscheduled visits necessary to perform an additional ECG called for by the study protocol will be paid in an amount equal to 30% of the Visit 3 compensation, stated above. For any other additional unscheduled visits no compensation will be paid.

Compensation

- "Completed" and "per protocol" patient applies to a patient:
- who was thoroughly informed about the study,
- gave Informed Consent in writing,
- did not violate either inclusion or exclusion criteria,
- took the investigational product according to the protocol,

Compensation

If a patient fails the screening process, the INVESTIGATOR will receive compensation in the amount of a Visit 1 rate, if the complete screening procedure (Visit 1 and Visit 2) was performed or if a patient fails the screening process due to laboratory values. A patient who fails the screening process already at Visit 1 will not be remunerated. The INVESTIGATOR will receive compensation for a number of screening failures that equals or is less than 50% of the number of patients randomised according to protocol. E.g.: If 8 patients are randomised according to protocol, a maximum of 4 screening failures will be compensated.

Compensation

If the study is terminated prematurely for any reason, proportional payments (plus non-cancellable study-related expenses…) will be made according to the above list, depending on the achieved study progress.

If unnecessary costs are negligently caused by the INVESTIGATOR, e.g. elevated courier costs due to late notification of the courier, cancellation of a monitoring visit at short notice (< 48h), inadequate preparation of documentation for a monitoring visit, CRO reserves the right to deduct these costs from the fee. (and what about Sponsor delays?)

Compensation

Mode of Payment

Under this agreement, the compensation according to the above list will be paid based on patient visits completed and CRFs reviewed and collected (How often will this occur?) by the responsible monitor. On a quarterly basis, the INVESTIGATOR will be paid up to 75% of the accrued compensation.

The final payment of the remaining 25% will be made when all queries have been satisfactorily resolved and all documents for all sites are completed and submitted to CRO. A payment overview will be made available to the INVESTIGATOR.

Compensation

Document Storage:

Study medical records and data shall be retained by RESEARCHERS for the earliest of: (i) at least 2 years after the last approval of the marketing application in the United States, European Union or Japan; (ii) 2 years following notification from Sponsor/CRO that it has formally discontinued clinical development of the Compound; (iii) such other minimum retention period requirements as required by applicable law; or (iv) 10 years. In the event Sponsor/CRO requires storage of documents beyond ten years, Sponsor/CRO and Institution may arrange for additional storage costs. Institution will notify Sponsor/CRO in writing prior to destruction of any Study medical records and, if requested by Sponsor/CRO, shall transfer such records to Sponsor/CRO at Sponsor/CRO's expense.

Top 10 Negotiation Roadblocks

(and some equally creative responses)

#10 No other site is asking for this…

May I put you on speaker so that you can repeat that and my boss can hear? I want her to know I'm doing my job.

#9 This budget is non-negotiable…

I am not negotiating with you, I am telling you we can't do this trial under these terms.

#8 That's your cost of doing business…

This is a study-specific item.

Top 10 Negotiation Roadblocks
(and some equally creative responses)

#7 The budget is the same for all sites…
Are the costs the same for all sites?

#6 That's covered in by the per-subject budget…
What else is covered by the per-subject budget?

#5 The payment system is already set up…
So is ours, and our staff expects to get paid every 14 days and our vendors every 30 days.

Top 10 Negotiation Roadblocks
(and some equally creative responses)

#4 The sponsor is not paying for that…
So who do you suggest does pay for this?

#3 We're striking the "IRB Submission Fee", we're paying for the IRB …
You're paying for the IRB to review the protocol.
You're paying us to prepare all the paperwork for the IRB to review and hopefully approve.

#2 We're only paying X over-head, just "pad" a line item.
OK, tell me where else you'd like me to lie to you.

The #1 Negotiation Roadblock

The Investigator Meeting is the Investigator's investment in the study…

We're sorry, we thought you were asking our investigator to work for you, if he wanted to invest he'd buy stock and at this time he's not investing.

OR

Explain the cost of PI and SC being out of the office, etc.

Our Personal Favorite

Ok, I'm willing to give you this, but you

have to promise to keep this a secret and not tell any other sites.

I can keep a much bigger secret than that!

Some Notes on Negotiation

The more time you take, the better your chances of pushing the other person the their bottom line.

Take all the time you've got, take more if you can get it. Negotiate the deadline as well.

In a "quickie" negotiation, the result usually goes too far in one direction. The skilled people come out better in a quickie. If you are not sure who is better in a quickie, it probably isn't you.

Some Notes on Negotiation

Competitive Mode: Don't give anyone any information unless you know exactly why you are doing so. Don't tip your hand unless to intentionally misdirect. Don't say things like "I have to have this done or I'm fired tomorrow" or "we need the work".

Lawyers ask you questions designed to make you talk, to extract data. The answer to "do you know what time it is?" is "Yes." Not "9:15"

Some Notes on Negotiation

Do not trust your estimates or assumptions. Watch out for “funny money” items. (Why do they use chips in Vegas?) Translate funny money items into real value items. Don’t get bamboozled by funny money items.

For example, calculate what the final withholding percentage equates to in actual dollars.

Some Notes on Negotiation

Beware the “personal” negotiation mode. You may be negotiating for things that you aren’t supposed to: workload, personality, trust, time constraints, ego.

Find out what is important to the other party. You may lose a deal, the other party will find a way to say “no” even if it’s in their company’s best interest to have the deal take place.

Some Notes on Negotiation

Concession-making:

Leave room to negotiate

Be stingy with your concession-making

Watch the rate of concessions

Don’t concede first on major issues.

Don’t concede tit-for-tat and don’t agree to “split the difference” (funny money)

Avoid massive concessions under deadline pressure.

Some Notes on Negotiation

Say “no” once more. If you give in too easily, you send the message that you were bluffing.

Legitimacy: “our company policy prohibits us from doing this” “it’s against company policy” “fair market value” – good rules and regulations make negotiation easier. “No haggle policy” means they don’t have to haggle with YOU.

Some Notes on Negotiation

Another tactic is to get the other party's expectations to go down.
Making people feel bad lowers their expectations.

"I think you can do better" – this works because sellers don't often have confidence in their own pricing structure. "Is that your best price?"

Thank you!

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