

Driving High Performance

Shortening study start-up and optimizing revenue generation

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What is our goal?

Achieve operational efficiency



How do we get there?

- Understanding your study pipeline
- Being prepared for contract and budget negotiations
- Knowing your accounts receivables
- Obtaining assistance when needed

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Study Pipeline

- Understand what indications your site excels at
- Be diversified in your capabilities
- Establish relationships with multiple sources for study opportunities
- Ensure study submissions are timely
- Track the status of all study leads/submissions
- Aim for studies in all stages at all times—don't let your pipeline dry up

PI	Status	Sponsor	CRO	Participating Site Status Comments
Smith, MD, PhD, Sonny	Enrolling	ABC Pharma Company	Great CRO	<p>PS Notes: 8/18/14 - Budget and contract pending with site.</p> <p>SCK Notes: 7/1/14 Jon sent over info for PI availability for IM. SCK sent to A&D. 7/2/14 D says she rec'd a selection letter during pipeline call.</p> <p>Regulatory: 7/7/14 D says still have not rec'd. 7/8/14 SCK asked Jon to find out when we can expect this. 7/9/14 Jon says his contact still doesn't have Reg either but that we will be first to know when it comes in. 7/17/14 SCK sent Reg to D.</p> <p>Budget: 7/1/14 PS handling...</p> <p>Contract: 7/1/14 PS handling... 8/6/14 patient reimbursement ended up being \$50. 8/28/14 Andy says that everything is final, we are simply waiting for the CRO to send out versions for signatures. 8/29/14 D confirmed that signed original CTAs have been sent to Andy today. 9/8/14 Anna sent FE versions of CTA to SCK and A. 9/10/14 D says that the SIV has been pushed back until November; the DEA situation is being fast-tracked by them. 10/29/14 D confirmed that still no date set for SIV as we are still waiting on the DEA. 11/12/14 D confirmed still no change, but that she filled out paperwork for the extension protocol (so there is some movement). 12/17/14 D says no news until after X-Mas. 12/18/14 rec'd notice that all payments will be made automatically electronically. 1/6/15 D says no update on SIV scheduling or DEA. 1/14/15 D says they rec'd a piece of paper from the DEA on Monday, but that his name is spelled incorrectly. 1/21/15 D says she has informed the DEA of the incorrect spelling and has no idea how long they will take to fix it.</p> <p>Advertising: None</p>
Jones, MD, Marti	In Start-up	Super BioPharma	CRO Today	<p>9/23/15 A&D notified on pipeline call that PI will have a PSV on 9/29/15. 9/29/15 A says PSV went very well. 10/19/15 Ashley says we got the study.</p> <p>Regulatory: Have you rec'd Reg yet?</p> <p>Budget: 10/19/15 Nothing yet</p> <p>Contract: 10/19/15 Nothing yet.</p>
Songi, MD, Alex	In Start-up	Super BioPharma	CRO Today	<p>8/25/15 Billy confirmed PSV date of 9/29/15 at 9am. 9/21/15 notified that there are 2 protocol numbers (1 includes PK and 1 without); Billy confirmed that they will be doing the PK portion. 9/29/15 A says PSV went well. 10/15/15 A forwarded selection notice. 10/20/15 D forwarded Site Info Sheet.</p> <p>Regulatory: Have you rec'd Reg yet?</p> <p>Budget: 10/19/15 Nothing yet (2 PIs selected so far)</p> <p>Contract: 10/19/15 Nothing yet.</p>
Cooper, MD, Bradley	Submitted	Unknown Sponsor	Unique CRO, LLC	<p>8/23/13 Anna sent email to CRO looking for an update to see if study was still supposed to be starting in September and whether any of our sites were being considered or rejected. 8/26/13 Anna received response from CRO, still no updates on SS. 9/30/13 no news on site selection or award decision. 11/19/13 SCK followed up for updates and to see if this is moving forward as scheduled. No updates on study, "still considered possible." 3/3/15 New questionnaire may go out but still viable.</p>
Larson, MD, Scotty	Submitted	Unknown Sponsor	Global CRO	<p>10/25/13 sub'd using automatic adobe form.</p>

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Contract Negotiations



- Due diligence is essential
- Protect your site's interests
 - Confidentiality
 - Indemnification
 - Subject injury
 - Termination
 - Sponsor/CRO obligations
- Identify your contract language “must have’s”
- Maintain preferred language samples for re-use
- Ensure payment terms align with the budget

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Budget Negotiations

- Establish what payment frequency you must have to stay in business
- Know your true costs to perform clinical research
- Identify what procedures must be outsourced and the full cost to your site
- Review the protocol in detail and note all questions, concerns and issues (preferably before the PSV but certainly during negotiations)
- Build out each study budget from zero-based on your actual costs versus the schedule of activities
- Maintain written cost justification to provide with requests

PER PATIENT COSTS:	Cost Per Unit	Units			Screening/V isit 1	Week 1/Visit 2	Week 2/Visit 3	Week 3/Visit 4	EOS/Visit 5	Total
Informed Consent	150.00	1.00			1.00					150.00
Inclusion/Exclusion Criteria	100.00	1.00			1.00					100.00
Demographics	25.00	1.00			1.00					25.00
Medical History	150.00	1.00			1.00					150.00
Concomitant Medications	75.00	5.00			1.00	1.00	1.00	1.00	1.00	375.00
Adverse Events	75.00	5.00			1.00	1.00	1.00	1.00	1.00	375.00
Complete Physical Exam	325.00	1.00			1.00					325.00
Targeted Physical Exam	225.00	4.00				1.00	1.00	1.00	1.00	900.00
Randomization	100.00	1.00			1.00					100.00
Vital Signs	50.00	5.00			1.00	1.00	1.00	1.00	1.00	250.00
Height	5.00	1.00			1.00					5.00
Weight	5.00	2.00			1.00				1.00	10.00
ECG	200.00	1.00			1.00					200.00
Hematology	65.00	5.00			1.00	1.00	1.00	1.00	1.00	325.00
Serum Chemistry	65.00	5.00			1.00	1.00	1.00	1.00	1.00	325.00
Urine Specimen	30.00	2.00			1.00				1.00	60.00
Study Drug Training	50.00	1.00			1.00					50.00
Study Drug Accountability	50.00	4.00				1.00	1.00	1.00	1.00	200.00
Diary Training	35.00	1.00			1.00					35.00
Diary Accountability	50.00	4.00				1.00	1.00	1.00	1.00	200.00
Totals		51.00			1,505.00	655.00	655.00	655.00	690.00	4,160.00
Non-procedure Fees										
Study Coordinator Fee				\$180	\$180	\$180	\$180	\$180	\$180	900.00
Investigator Fee				\$225	\$225	\$225	\$225	\$225	\$225	1,125.00
Data Entry Fee				\$30	\$30	\$30	\$30	\$30	\$30	150.00
SUB-TOTAL PER PATIENT COSTS					1,940.00	1,090.00	1,090.00	1,090.00	1,125.00	6,335.00
OVERHEAD				25%	485.00	272.50	272.50	272.50	281.25	1,584.00
PATIENT STIPEND					60.00	60.00	60.00	60.00	60.00	300.00
TOTAL PER PATIENT COST					2,485.00	1,422.50	1,422.50	1,422.50	1,466.25	8,219.00

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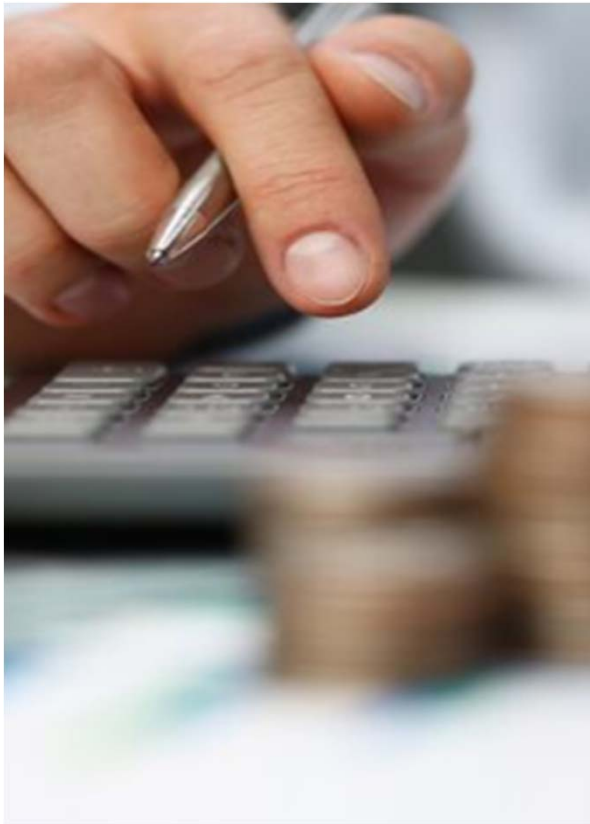
Accounts Receivable Management

For each study, can you answer the following:

- What income is coming in the door?
- What payments are going out the door?



Accounts Receivable Management



- Who will be responsible for accounts receivable management internally?
- Thoroughly understand the contractual payment terms
 - When are payments going to be issued?
 - What items must be invoiced?
 - Is there a deadline for submitting invoices?
- What is covered in the specific study budget?
 - Are advertising funds available?
 - Is training paid for?
 - What is the reimbursement for chart reviews?
- Track what work has been conducted
 - Monitoring visits
 - Protocol amendments
 - IND reports
- Submit invoices in a timely manner

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Accounts Receivable Management

- Follow up on payments in a timely fashion
- Reconcile each payment received versus the actual contracted budget
- Determine if you have left any money “on the table”
- Audit every study once it is complete to ensure you have received the full funds you are entitled to

Outsourcing



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Is outsourcing right for your organization?

Things to consider:

- What are your strengths?
- What is the capacity of your staff to perform “administrative” tasks?
- Is it financially beneficial if you outsource?

Outsourcing

Capacity

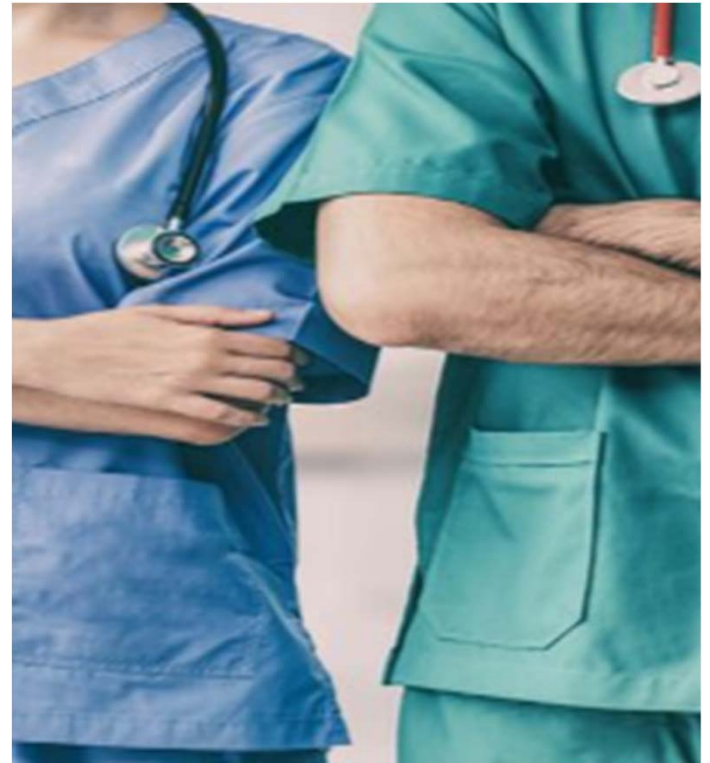
Can current staff perform the following tasks:

- Conduct business development
- Manage the study pipeline
- Negotiate contracts/budgets
- Recruit subjects
- Submit invoices
- Follow up on payments
- Reconcile financial records

AND

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Outsourcing



How much does it cost to outsource?

- Is your vendor's compensation aligned with your site's success?
- Are you paying a flat monthly fee?
- Do you pay on a "per consumption" basis?
- What value do you get for the money you pay?

In the end, what is most cost effective?

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Questions?

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