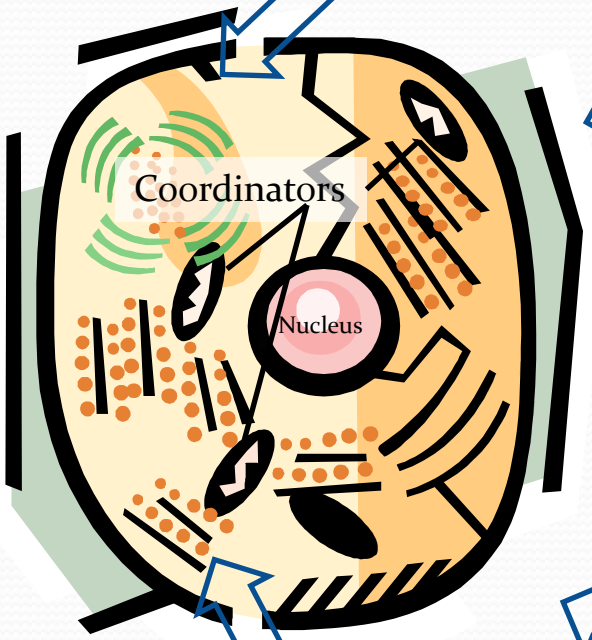
How to Build a Profitable Clinical Trials Business Model

Common Clinical Trials Business Model
Simple Business Model Structure
Key Business Standards
Application of Production Model to Clinical Trials
Getting Paid for Your Work

Greg Lampros
Department Administrator
OHSU- Knight Cardiovascular Institute
OHSU- School of Medicine

Common Clinical Trials Business Model

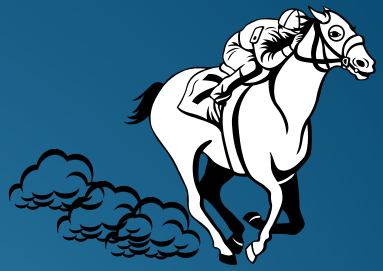
Human Cell Design



Demands
Contracts
IRB
Budgets
Protocols
PI
Sponsor
Billing
Research offices
Clinical Billing
Receivables
Pharmacy
Central Labs
Recruiting
Subjects
FDA
Paperwork
Storage

If you are here !

And want to go here



Simple Business Model Structure

Successful Business Models are Built on a Simple Process

Ideas germinate a need.

The need germinates productivity.

Productivity germinates a product.

A product germinates a cost.

A cost + a mark-up germinates a price.

An agreed upon price germinates a contract.

A contract germinates delivery of the product.

Delivery of the product germinates an invoice (time is money!)

An invoice germinates a receivable.

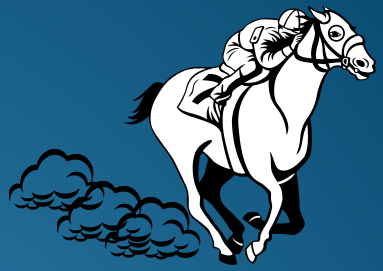
Collection of the receivable germinates the finalization of the sale.

Finalization of the sale germinates capital to invest in the business.

No matter what business you are in, all stakeholders: employees, researchers, sponsors, etc. need to understand this simple business process.

If you are here !

And want to go here



Key Business Standards

Primary Business Standards

First and above all

CASH is the critical element to a successful business
No CASH = no business = no jobs = failure.

As an administrator, who is overseeing clinical trials, your priority must be to generate CASH.

Primary Business Standards

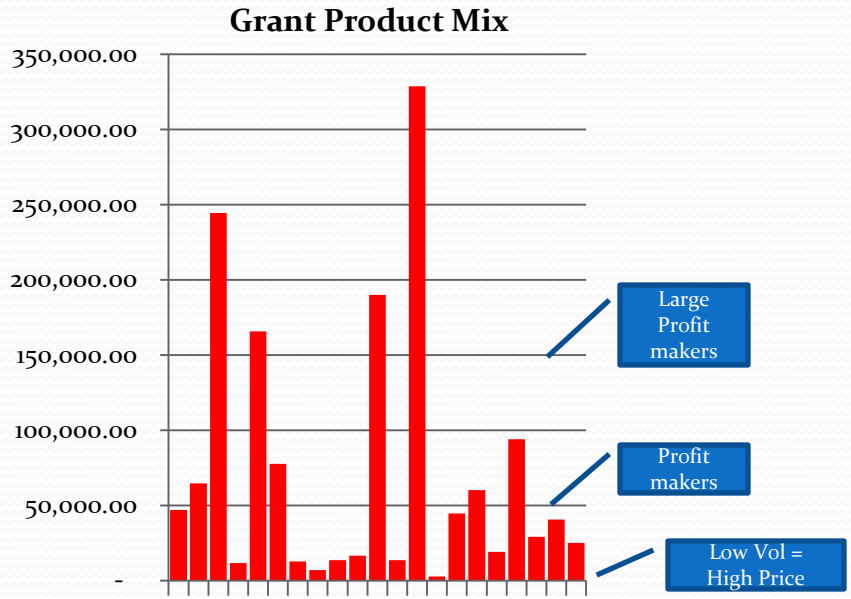
What Generates Cash?

PRODUCTS

How Do Businesses Use Products?
Product Mix: Volume v. Price

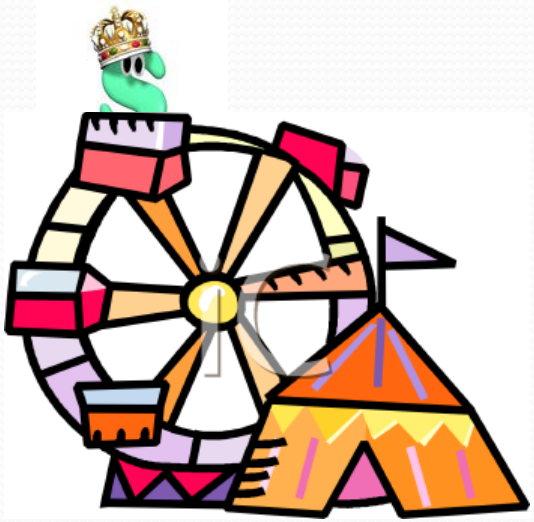
Loss Leaders: Milk and Bread, Studs and Hammers

Profit Makers: Items in Isles on the way to Milk and Bread
Doors and Trims



Primary Business Standards

Second: What makes CASH go round and round?



SALES & MARKETING

Primary Business Standards

Third: What is the basis for successful SALES AND MARKETING?

SPONSOR

RELATIONSHIPS

RELATIONSHIPS

RELATIONSHIPS

Who is the Primary Customer?

The one who pays the bills.

Who are the Secondary Customers?

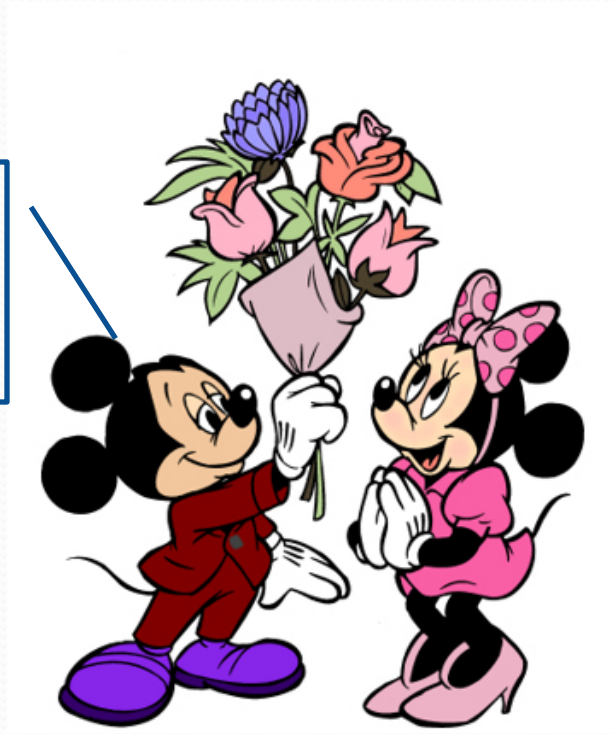
The ones who generate the work so the primary customer WILL pay the bills.

Primary Business Standards

Four: PERCEPTION is the key to Sales & Marketing.

How we want to be perceived by our Researchers and our Departments.

How we want to be perceived by our Sponsors and the regulatory bodies.



How we want to be perceived by our Patients.

A clinical trials business needs to have the skill sets to **NEGOTIATE** with all of these stakeholders.

Fifth: Doing What You Say: Communication E-Mail v. Phone

One of the best ways to destroy or not create a relationship, is to not answer e-mails in a timely fashion (same day, best same hour).

By Ignoring e-mails, you are saying "you are not that important to me."

"I am so special that my time is more important than yours."

While your ignoring someone's e-mail request, I am responding within a few minutes. In my case, I get the sale, in your case, you have no idea what you missed out on.

> Doing what you say you are going to do is the key to business execution and success. E-mail is a great tool in helping you to accomplish this key business standard.

Better Yet…Give them a call!!

Primary Business Standards

Sixth: Efficient productivity requires specialization.

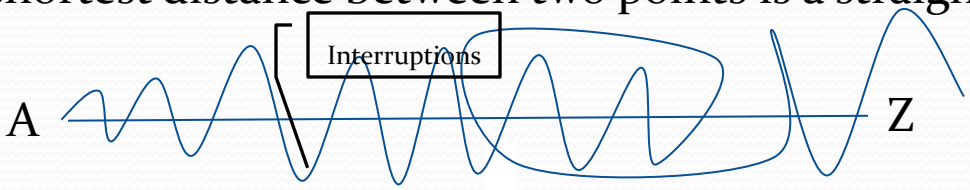
MULTI-TASKING IS GOOD?

SPECIALIZATION IS BETTER!

Primary Business Standards

Seventh: Redundancy is the evil prince of the king of CASH.

The shortest distance between two points is a straight line.



Multi-tasking can increase redundancy.

"Stop multi-tasking. Your brain is not wired to do 2,3,or more things at a time. You are not focused on any one of them."

Ann Webster, Ph.D. Benson Henry Institute for Mind/Body Medicine

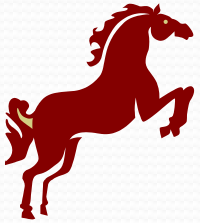
Specialization can reduce redundancy.

Whether you are working in a multi-tasking or a specialization model, how do you improve efficiencies and reduce redundancy and error rates?

It Starts with the Business Manager

Do You View Your Business as a Production Assembly Line?

If no = 

If yes = 

Identify the Steps of Production

30

Identify the Steps of Production

Trial Begins

IRB Approval

7-8 Sponsor Site interaction

Steps 1-6 Inquiry

9-10 Budget Negotiations

11-23 Regulatory Docs Complete & Submitted

24-26 Contract Complete

27-29 Internal Billing accts set up

STEP COMPLETED

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Sponsor contacts CMCT	CDA/NDA sent to CTO	CTO makes corrections	CMCT and sponsor sign CDA	Initial site selection	Site questionnaire completed	Pre-study site visit	Sponsor approves site selection	Sponsor sends study protocol, proposed budget, CTA	CMCT prepares proposed budget and sends to sponsor	Final budget negotiated with sponsor	PRQ completed and signed	Lay Language Protocol summary	Consent and HIPAA Auth. forms completed	Clinical billing schedule completed	IRQ completed	Any additional forms required completed	CMCT submits to IRB	CMCT sends contract to CTO	Sponsor regulatory documents completed	IRB gives conditional approval for CT	CMCT sends back to IRB any conditions for CT	Final Radiation Approval	IRB gives FINAL approval	Device Studies - Medicare submission (if applicable)	CTO negotiates final contract	Sponsor and OHSU sign final contract	Internal OHSU accounts set up	Research rate account set up	STUDY SET-UP	Clinical trial begins (ESTIMATED DATE)
10/8/2010	10/8/2010	Dr. Wei signed	Dr. Wei signed	x	N/A	10/14/2010	2/7/2011	2/7/2011	negotiations														N/A						

Key individual assignments tracked

This is what we have already done and this is what we need to finish

Notes:
11/8/10: Sponsor waiting on final FDA approval

1/4/11: Sponsor waiting on final FDA approval

1/26/11: Sponsor received final FDA approval; waiting on internal sign-offs
2/7/11: Sponsor began sending documents (protocol, budget)

LIZ (Research Coordinator):
Initial responsibilities:

1) Study team protocol evaluation

2) Monitor visit
3) Study "set-up"

FATEMA (Regulatory Specialist):
Initial responsibilities:

1) Study team protocol evaluation

2) Feasibility questionnaire
3) IRB submission (steps 11-17)
4) Regulatory documents
5) IRB conditions (steps 19-23)
6) Research rate set-up (step 28)

KEVIN (PROJECT MANAGER):
1) Study team protocol evaluation
2) Budget negotiations
3) CRO communications
4) Contract communications
5) Internal account set up
6) Overall project management

PI (Kevin Wei):
1) Study team protocol evaluation
2) Monitor visit
3) Budget sign off
4) Assist with IRB submission

JACI (Contract Analyst):
1) Contract negotiations
2) Contract signing
3) SPA communications - Internal account setup

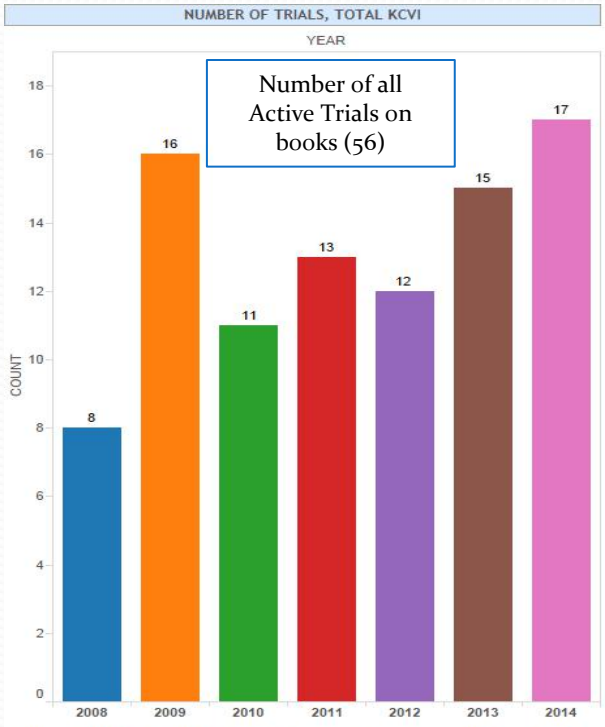
Identify the Steps of Production

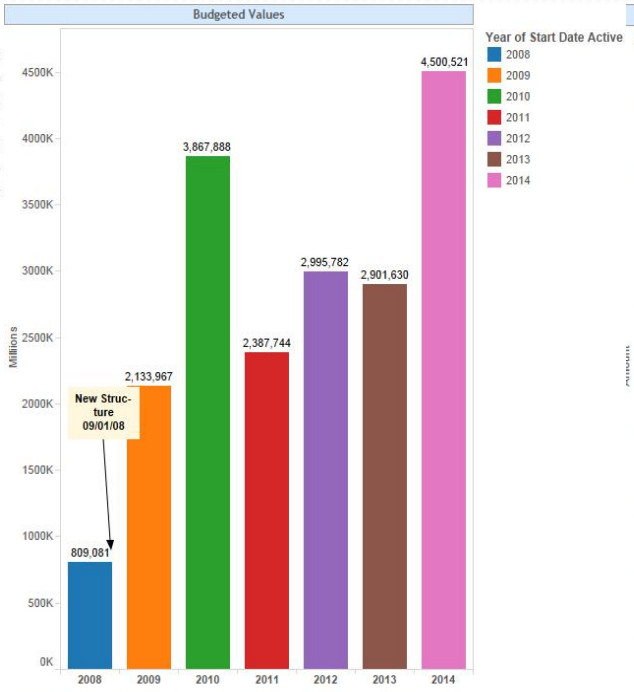
Historically what has been the Case success of going from

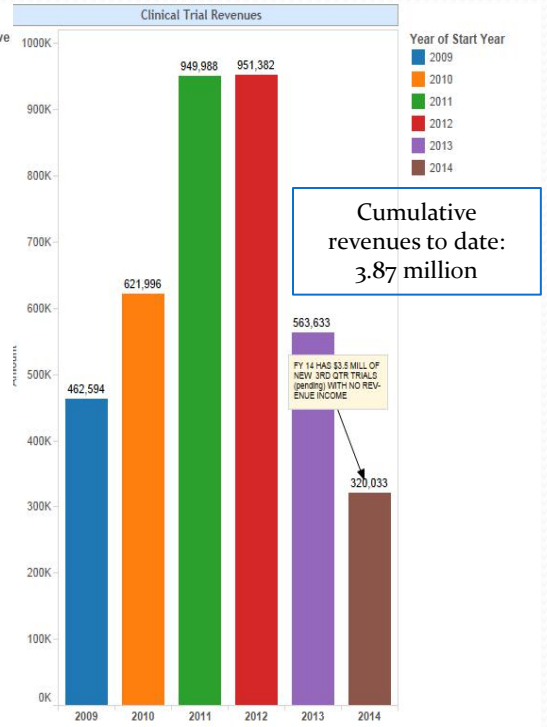
This

To This ?

										Regulatory specialist completes											Regulatory spec continues						SPA	REG SPEC	
STEP COMPLETED																												
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Sponsor contacts CMCT	CDA/NDA sent to CTO	CTO makes corrections	CMCT and sponsor sign CDA	Initial site selection	Site questionnaire completed	Pre-study site visit	Sponsor approves site selection	Sponsor sends study protocol, proposed budget, CTA	CMCT prepares proposed budget and sends to sponsor	Final budget negotiated with sponsor	PIQ completed and signed	Lay Language Protocol summary	Consent and HIPAA Auth. forms completed	Clinical billing schedule completed	IRQ completed	Any additional forms required completed	CMCT submits to IRB	CMCT sends contract to CTO	Sponsor regulatory documents completed	IRB gives conditional approval for CT	CMCT sends back to IRB any conditions for CT	Final Radiation Approval	IRB gives FINAL approval	Device Studies - Medicare submission (if applicable)	CTO negotiates final contract	Sponsor and OHSU sign final contract	Internal OHSU accounts set up	Research rate account set up	STUDY SET-UP	Clinical trial begins (ESTIMATED DATE)
10/8/2010	10/8/2010	Dr. Wei signed	Dr. Wei signed	x	N/A	10/14/2010	2/7/2011	2/7/2011	negotiations														N/A						







If you are here !

And want to go here

Applying Key Business Standards to the Production Model

RELATIONSHIP BUILDING

										Regulatory specialist completes				Regulatory spec continues								SPA	REG SPEC				
STEP COMPLETED																											
1	2	3	4	5	6	7		8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Sponsor contacts CMCT	CDA/NDA sent to CTO	CTO makes corrections	CMCT and sponsor sign CDA	Initial site selection	Site questionnaire completed	Pre-study site visit	Sponsor approves site selection	Sponsor sends study protocol, proposed budget, CTA	CMCT prepares proposed budget and sends to sponsor	Final budget negotiated with sponsor	PPQ completed and signed	Lay Language Protocol summary	Consent and HIPAA Auth. forms completed	Clinical billing schedule completed	IRQ completed	Any additional forms required completed	CMCT submits to IRB	CMCT sends contract to CTO	Sponsor regulatory documents completed	IRB gives conditional approval for CT	CMCT sends back to IRB any conditions for CT	Final Radiation Approval	IRB gives FINAL approval	Device Studies - Medicare submission (if applicable)	CTO negotiates final contract	Sponsor and OHSU sign final contract	Internal OHSU accounts set up	Research rate account set up	STUDY SET-UP	Clinical trial begins (ESTIMATED DATE)
10/8/2010	10/8/2010	Dr. Wei signed	Dr. Wei signed	x	N/A	10/14/2010	2/7/2011	2/7/2011	negotiations															N/A						

Steps 0: Identifying specialization: Obtaining investment support

Steps 0: Key specialists for clinical trials: Regulatory Specialist / Finance Business Manager

Steps 1-8: **Relationship Building**: Initial Contact, Confidentiality Agreement, Site visit & selection. Sponsor inter-relates to all members of team.

Steps 9-10: **Relationship Building**: Budget negotiations

Steps 11-26: **Relationship Building**: Regulatory documents submitted and finalized with Contracts Office, IRB, Sponsor

Steps 30+: Relationship Building: Subject Recruitment, Consent, Trial begins .

CASH FLOW

										Regulatory specialist completes								Regulatory spec continues							SPA	REG SPEC	
STEP COMPLETED																											
1	2	3	4	5	6	7		8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Sponsor contacts CMCT	CDA/NDA sent to CTO	CTO makes corrections	CMCT and sponsor sign CDA	Initial site selection	Site questionnaire completed	Pre-study site visit	Sponsor approves site selection	Sponsor sends study protocol, proposed budget, CTA	CMCT prepares proposed budget and sends to sponsor	Final budget negotiated with sponsor	PPQ completed and signed	Lay Language Protocol summary	Consent and HIPAA Auth. forms completed	Clinical billing schedule completed	IRQ completed	Any additional forms required completed	CMCT submits to IRB	CMCT sends contract to CTO	Sponsor regulatory documents completed	IRB gives conditional approval for CT	CMCT sends back to IRB any conditions for CT	Final Radiation Approval	IRB gives FINAL approval	Device Studies - Medicare submission (if applicable)	CTO negotiates final contract	Sponsor and OHSU sign final contract	Internal OHSU accounts set up	Research rate account set up	STUDY SET-UP	Clinical trial begins (ESTIMATED DATE)
10/8/2010	10/8/2010	Dr. Wei signed	Dr. Wei signed	x	N/A	10/14/2010	2/7/2011	2/7/2011	negotiations															N/A						

Steps 9-10: **Budget Negotiations**: This is the critical element to obtaining the necessary **CASH** for the business to succeed.

What is considered a successful negotiation?

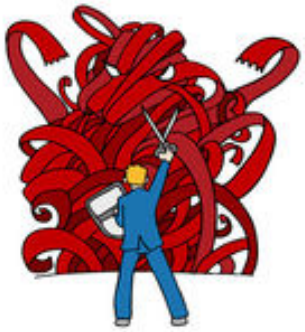
50 / 50: Let's Split the Difference

The ability to tell a person to go to hell so that he actually looks forward to the trip!

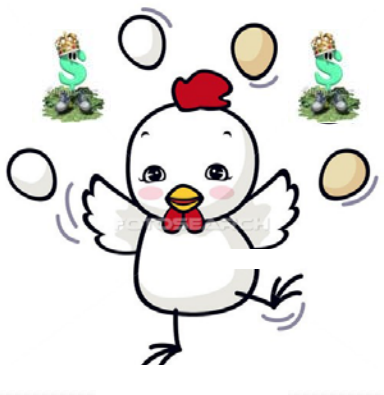
Remember: Sponsors always have more money to give you then they let on. Your role is to build a trusting relationship so that they are happy to hand it over to you---you don't want to leave money on the table. You need to calculate a reasonable non-refundable admin fee for steps 1-30… lots of work with no income. Hold off IRB submission til this step is complete

SPECIALIZATION

To build a clinical trials business based on a productivity model requires work specialization, which requires an investment. This can lead to a chicken and egg dilemma.



We have found that the most critical element for building a successful clinical trials business is the **Regulatory Specialist.**



The second most critical element is the **<u>One-Contact</u>** finance **Business Manager.**

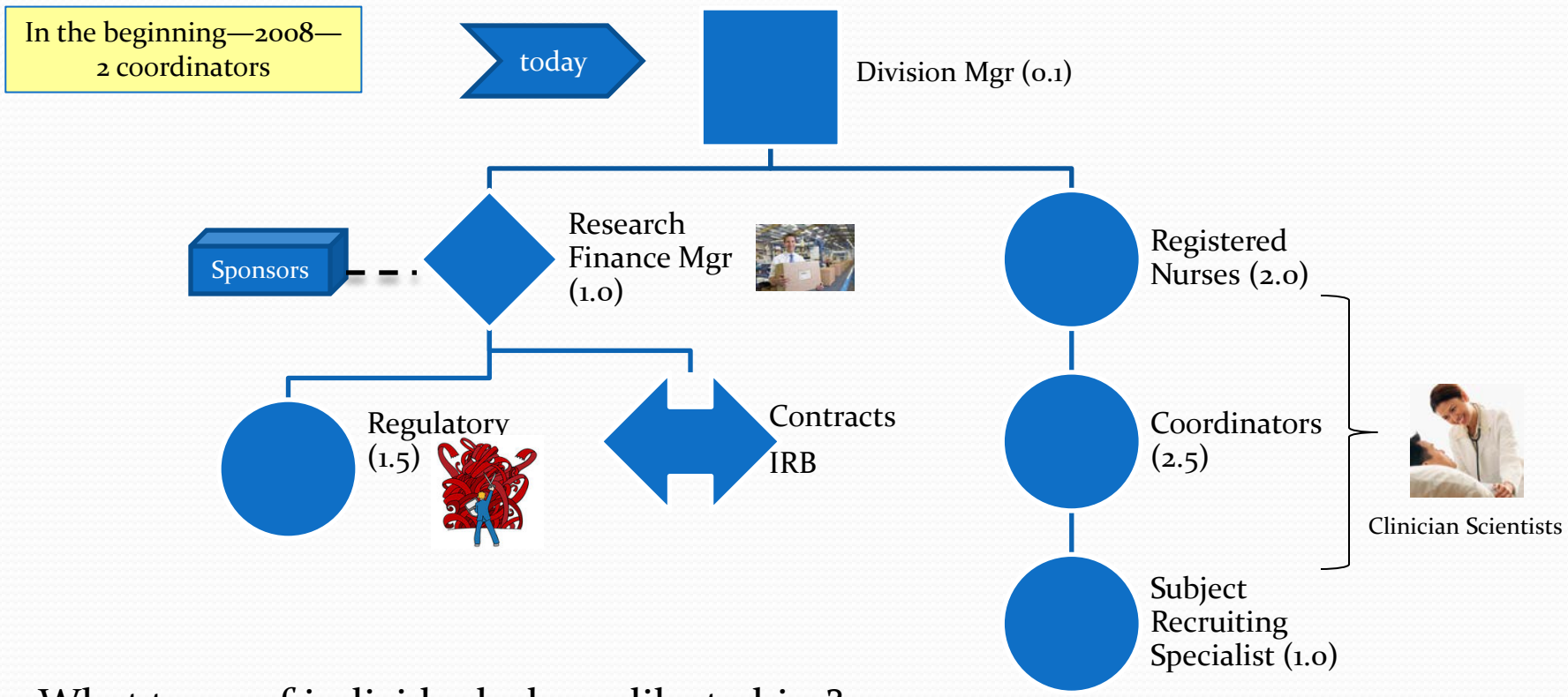
In General: As a consumer, how many contacts do you want to deal with when you call a business?

As a consumer, how many of you like making a call and getting an extensive telephone tree to choose options?

As a consumer, how many of you want to talk to a person directly when dealing with matters of importance?

To secure investment, one must sell this philosophy to your department chairs.

2014 Organizational Structure



What types of individuals do we like to hire?

Individuals who can take the organization where we want to go, rather than where we have been.
Definitely people who know how to play outside the box.

Our financial analytics group is made up of: a PhD scientist, theoretical mathematician, forensic accountant, corporate business manager, and a Yale historian.

Did I Mention RELATIONSHIP BUILDING?

The Critical Feature of the Budget

MARGINS: Don't be Shy.

In preparing a budget, due diligence requires that a satisfactory margin is developed as an outcome of the budget process. Margins need to cover operational costs, overhead costs, and **cash reserve requirements:** determined in advance by the business manager.

Procedure	Bracco proposed unit offer	# of units	# of patients	Bracco total proposed offer	OHSU proposed unit offer	OHSU total proposed offer
CF Administration	$50	1	10	$500	$50	$500
Medical History	$125	1	10	$1,250	$125	$1,250
Pregnancy Test	$20	1	5	$100	$20	$100
AE Monitoring	$100	1	10	$1,000	$100	$1,000
Physical Exam	$150	2	10	$3,000	$150	$3,000
Vital Signs	$25	10	10	$2,500	$25	$2,500
ECG Collection	$25	9	10	$2,250	$25	$2,250
12-lead ECG(day 2)	$0	1	10	$0	$200	$2,000
Laboratory Sample Collection	$50	2	10	$1,000	$50	$1,000
RAP/RVP	$30	1	10	$300	$30	$300
PAPs, PAPd, MPAP	$30	10	10	$3,000	$30	$3,000
PCWP, Qp, HR)	$30	5	10	$1,500	$30	$1,500
Investigator	$1,500	1	10	$15,000	$1,500	$15,000
Research Staff (Research Coordinator)	$750	1	10	$7,500	$1,000	$10,000
Administrative staff (regulatory/finance/mgmt)	$0	1	10	$0	$500	$5,000
DDP	$500	1	10	$5,000	$500	$5,000
Pre&Post Visits	$50	2	10	$1,000	$50	$1,000
Patient stipend	$0	1	10	$0	$100	$1,000
BASE EVALUABLE SUBJECT				$44,900		$55,400
University F&A (overhead) - 25%				$11,225		$13,850
TOTAL EVALUABLE SUBJECT				$56,125		$69,250

In this budget, the highlighted areas are those where the sponsor either offered "0" compensation, or we increased the compensation. In this case, the total subject compensation was increased by 23%.

SPONSOR budget proposal for pass-through costs/charges billed to clinical trial study (invoiced to sponsor separately):			
IRB initial review	$ 2,500.00	$ 2,200.00	Pass Through
IRB annual or continual reviews (if required)	$ -	$ 1,320.00	
IRB amendments (if required)	$ -	$ 825.00	
IRB administrative termination (if required)	$ -	$ 550.00	
Archiving/Storage fee	$ -	$ 750.00	Billed to study upon completion
Hotel (if required for 2nd day visit)	$ -	$ 250.00	If required
Pharmacy set-up (NOT subject to overhead)	$ -	$ 750.00	
Pharmacy monthly maintenance (subject to 25% overhead)	$ -	$ 187.50	Pass through
Pharmacy dispensing (subject to 25% overhead)	$ -	$ 20.94	
Non-refundable administrative fee (set-up)	$ 1,000.00	$ 4,500.00	Billed to study

This part of the budget is the pass-through charges. In this case, the sponsor only offered $2,500 for IRB fees. We renegotiated all potential IRB fees: continual reviews, amendments, termination, etc. Fees were agreed upon and built into the contract.

In addition to the IRB fees, we negotiated Storage fees, Hotel fees, Pharm set-up fees, and a Non-refundable Admin fee of $5,500.

MARGINS: Don't be shy

50%

The chance that someone will always say YES to a counter offer!

$800.00

SPECIALISTS ROLES

										Regulatory specialist completes								Regulatory spec continues								BA	REG SPEC	
STEP COMPLETED																												
1	2	3	4	5	6	7		8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Sponsor contacts CMCT	CDA/NDA sent to CTO	CTO makes corrections	CMCT and sponsor sign CDA	Initial site selection	Site questionnaire completed	Pre-study site visit	Sponsor approves site selection	Sponsor sends study protocol, proposed budget, CTA ∞	CMCT prepares proposed budget and sends to sponsor	Final budget negotiated with sponsor	PPQ completed and signed	Lay Language Protocol summary	Consent and HIPAA Auth. forms completed	Clinical billing schedule completed	IRQ completed	Any additional forms required completed	CMCT submits to IRB	CMCT sends contract to CTO	Sponsor regulatory documents completed	IRB gives conditional approval for CT	CMCT sends back to IRB any conditions for CT	Final Radiation Approval	IRB gives FINAL approval	Device Studies - Medicare submission (if applicable)	CTO negotiates final contract	Sponsor and OHSU sign final contract	Internal OHSU accounts set up	Research rate account set up	STUDY SET-UP	Clinical trial begins (ESTIMATED DATE)
10/8/2010	10/8/2010	Dr. Wei signed	Dr. Wei signed	x	N/A	10/14/2010	2/7/2011	2/7/2011	negotiations															N/A						

Steps 1-10: **Business Research Manager**: Initial contact, feasibility assessment, confidentiality agreement, site visit & selection, budget negotiation, letter of intent, contract process begins.

Steps 11-26: **Regulatory Specialist** completes all regulatory submission documents: PPQ, Lay Language, Consent, Billing Schedule, IRQ, IRB Submission, Sponsor Regulatory docs, Edits, **PI involvement,** Complete IRB submission. Complete contract negotiations in parallel with IRB submission process.

Steps 27-30: **Research Coordinator:** Study Set up.

Steps 30+: Research Coordinators **focus on recruiting subjects**.
Business Manager focuses on Billing Sponsor and Collecting Receivables

Sales and Marketing

SALES & MARKETING

											Regulatory specialist completes								Regulatory spec continues						SPA	REG SPEC
STEP COMPLETED																										
1	2	3	4	5	6	7		8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Sponsor contacts CMCT	CDA/NDA sent to CTO	CTO makes corrections	CMCT and sponsor sign CDA	Initial site selection	Site questionnaire completed	Pre-study site visit	Sponsor approves site selection	Sponsor sends study protocol, proposed budget, CTA	CMCT prepares proposed budget and sends to sponsor	Final budget negotiated with sponsor	PPQ completed and signed	Lay Language Protocol summary	Consent and HIPAA Auth. forms completed	Clinical billing schedule completed	IRQ completed	Any additional forms required completed	CMCT submits to IRB	CMCT sends contract to CTO	Sponsor regulatory documents completed	IRB gives conditional approval for CT	CMCT sends back to IRB any conditions for CT	Final Radiation Approval	IRB gives FINAL approval	Device Studies - Medicare submission (if applicable)	CTO negotiates final contract	Sponsor and OHSU sign final contract	Internal OHSU accounts set up	Research rate account set up	STUDY SET-UP	Clinical trial begins (ESTIMATED DATE)
10/8/2010	10/8/2010	Dr. Wei signed	Dr. Wei signed	x	N/A	10/14/2010	2/7/2011	2/7/2011	negotiations															N/A						

Congratulations: You have just completed the 30-step process and the Sponsor just announced they are closing your site.

WHAT HAPPENED??

Have a Recruiting Plan

SALES & MARKETING

Most sponsors will be patient on your process if you include a "Recruiting Plan" in your correspondence.

GENERAL INFORMATION		
Study Title		
Principal Investigator	**Research Coordinator**	
Co-Investigators		
Enrollment Goal	**Enrollment start date**	**Estimated enrollment end date**
Location(s) Subjects will be recruited		
RECRUITMENT STRATIGY		
Recruitment tools to be used *Attach all recruitment tools to final plan* Study posters Patient mailings Online advertisements (craigslist, cardiology website etc.)	**Subject compensation offered** $	
Who is fully responsible for recruiting?		
Detailed Recruitment plan		

MEET AS A GROUP
Make your plan formal!

And this is a great Relationship Tool!

<u>Recruiting Plan Data</u>:
- Feasibility, # of patients that may be eligible, etc. (**Robust data platform**)
- - Newspaper, Radio Ads
- Patient Letters
- Internal Posters
- Recruiting focus. Outpt, Inpt, Procedural Labs. When, where, how often, subject matter.
- Inclusion / Exclusion referral sheets:
- Newsletters, update, "whose on top!"

By telling the sponsor, "**this is our recruiting strategy**" you will earn greater respect and more support for what you want to do. And what does this equal?

Getting the Bills Paid

ACCOUNTS RECEIVABLE

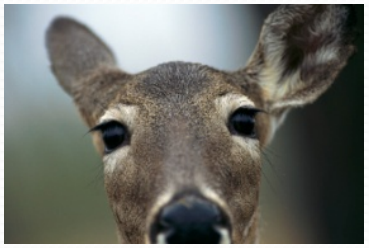
If you ask someone what an Account Receivable is and they have this look

You can fairly well assume that you are not going to get all of your money!

Unfortunately, experience tells us that most researchers and clinical trial coordinators fall within this category.

ACCOUNTS RECEIVABLE

Solution



You need someone trained and experienced in business to run a business.

ACCOUNTS RECEIVABLE

EchoCRT

Patient Initials	Patient Number		DATA SET A Enrollment & Baseline		DATA SET B Implant	DATA SET C Pre-discharge	DATA SET D Randomization			DATA SET E	DATA SET F	DATA SET G		DATA SET H	DATA SET G		DATA SET H	DATA SET F	DATA SET H	DATA SET I	DATA SET J	DATA SET J	DATA SET J	DATA SET J	Early Termination or Hospitalization/Mortality (Data Set K)
			ICF/ECG	Echo	Visit eCRF	Visit eCRF	Random. eCFR	AV delay optimiz.	2nd baseline (if applic)	Month 1	Month 3	Month 6	Month 6	Month 9	Month 12	Month 12	Month 15	Month 18	Month 21	Month 24	Month 27	Month 30	Month 33	Month 36	Enter Date and Reason
RJH	1	Projected																							
		Actual	9/28/09	10/15/09	10/28/09	10/29/09	10/29/09	10/29/09		12/3/09	2/4/10	5/27/10													6/23/2010 Deceased
TMR	2	Projected																							
		Actual	10/28/09																						Screen Failure
DMF	3	Projected																							
		Actual	12/7/09																						Screen Failure
MGH	4	Projected																							
		Actual	1/4/10	1/11/10	1/19/10	1/21/10	1/22/10	1/22/10		2/18/10	4/28/10	9/2/10		11/18/10	2/18/11		5/24/11								
AS	5	Projected														NO									
		Actual	2/8/10	2/8/10	2/16/10	2/17/10	2/17/10	2/17/10		not done	5/27/10	9/2/10		10/21/10	3/24/11	ECHO									
N-T	6	Projected																							
		Actual	6/17/10	6/17/10	6/25/10	N/D	8/12/10	8/12/10		9/16/10	10/21/10	1/12/11		4/8/11											
S-W	7	Projected																							
		Actual	7/21/10	7/21/10																					Screen Failure
MMR	8	Projected	11/4/10	11/4/10	12/1/10	12/2/10	12/1/10	12/2/10																	
		Actual	11/4/10	11/4/10	12/1/10	12/2/10	12/1/10	12/2/10		1/3/11	4/18/11	6/23/11	6/23/11												
LGB	9	Projected																							
		Actual	2/14/11	2/14/11	3/10/11	3/11/11	3/11/11	3/11/11		4/8/11	6/24/11														
CIM	10	Projected			Screenfail	Screenfail	Screen fail																		
		Actual	3/15/11	3/15/11																					

Subject Initials	Subject Number		Screening/Enrollment	24 hour visit	ACCRUED	PAID	Subject A/R
ADVANCE	ADVANCE					INITIAL	
						$6,925.00	-$6,925.00
C-D	651					CK2	
		Actual	6/1/11	6/2/11	$6,925.00	$6,925.00	$0.00
T-C	601						
		Actual	6/9/11	6/10/11	$6,925.00		$6,925.00
C-W	652					CK1	
		Actual	6/15/11	6/16/11	$6,925.00	$6,925.00	$0.00
H-W	653					CK1	
		Actual	6/15/11	6/16/11	$6,925.00	$6,925.00	$0.00
E-A	602	Projected				CK2	
		Actual	7/21/11	7/22/11	$6,925.00	$6,925.00	$0.00
R-P	654	Projected				CK2	
		Actual	7/21/11	7/22/11	$6,925.00	$6,925.00	$0.00
L J J	603	Projected				CK2	
		Actual	7/27/11	7/28/11	$6,925.00	$6,925.00	$0.00
RGE	604	Projected					
		Actual	8/4/11	8/5/11	$6,925.00		$6,925.00
MFL	655	Projected					
		Actual	8/10/11	8/11/11	$6,925.00		$6,925.00
HMP	605	Projected					
		Actual	8/10/11	8/11/11	$6,925.00		$6,925.00
B-A	656	Projected					
		Actual	8/22/11	8/23/11	$6,925.00		$6,925.00
GAW	606						
			8/31/11	9/1/11	$6,925.00		$6,925.00
							$34,625.00

Subject Data Set List generates accounts receivable table

Accrued A/R becomes part of the Grant monthly P&L report

Financial report as of 8/31/2011

SUBJECTS ENROLLED: 12

	July 2011	August 2011	Total to-date
REVENUE			
Billed and collected	13,850.00	27,700.00	56,300.00
Billed and NOT collected (A/R):	0.00	0.00	35,938.78
Total Revenue:	**13,850.00**	**27,700.00**	**92,238.78**
EXPENSES			
Personnel:			
Unclassified Salaries	0.00	1,962.67	1,962.67
Subtotal Personnel	0.00	1,962.67	1,962.67
Fringe Benefits			
OPE Unclassified	0.00	765.61	765.61
Subtotal Fringe Benefits	0.00	765.61	765.61
Services & Fees			
Departmental Assessment	692.50	0.00	748.75
Departmental Assessment accrual	0.00	0.00	3,181.94
Miscellaneous Fees & Svcs	0.00	0.00	0.00
OHSU IRB Fees	0.00	0.00	2,200.00
Pharmacy setup	750.00	0.00	750.00
Research Subjects	200.00	400.00	900.00
Subtotal Services & Fees	1,642.50	400.00	7,780.69
Supplies			
Pharmaceuticals	300.00	150.00	450.00
Subtotal Supplies	300.00	150.00	450.00
Travel			
Travel-Domestic (Hotels)	246.63	174.38	421.01
Subtotal Travel	246.63	174.38	421.01
Other			
Hosting Groups & Guests	0.00	345.00	345.00
Subtotal Other	0.00	345.00	345.00
Patient Care			
FPP Provided Med Services	0.00	0.00	0.00
Medical Service	112.29	65.05	177.34
Subtotal Patient Care	112.29	65.05	177.34
Total Direct Costs:	2,301.42	3,862.71	11,902.32
Total F&A Costs:	171.79	772.55	1,004.34
TOTAL PROJECT EXPENSES:	**2,473.21**	**4,635.26**	**12,906.66**
NET PROFIT:	**11,376.79**	**23,064.74**	**79,332.12**

ACCOUNTS RECEIVABLE

Why you need a Business Manager to oversee clinical trials.

200 rows. Green shaded areas are all trials complete.

Yellow is potential receivables.

The Final Piece

THE FINAL PIECE

What does the Contract obligate the parties to?

Sponsor's View:

High enrollment
Collection and entry of Data
Successful close

Our View:

We have provided you with:
High enrollment
Collection and entry of Data
Successful close

Your end of the contract agreement is to:

Pay the bill!!

Don't be shy in asking the Sponsor to live up to their end of the agreement!

Did I Mention RELATIONSHIP BUILDING?