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

Coordinators

Nucleus
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
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

CASH IS KING!!
Primary Business Standards

Second: What makes **CASH** go round and round?

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

Who are the Secondary Customers?

Who is the Primary Customer?
The one who pays the bills.
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 Sponsors and the regulatory bodies.

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

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.
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!**
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 = [Image]

If yes = [Image]

Identify the Steps of Production

30
### Identify the Steps of Production

#### 1-6 Inquiry
- Steps 1-6 Inquiry
- Sponsor contacts CMCT
- CDA/NDA sent to CTO
- CTO makes corrections
- CMCT and sponsor sign CDA

#### 7-8 Sponsor Site interaction
- Initial site selection
- Site questionnaire completed
- Pre-study site visit
- Sponsor approves site selection

#### 9-10 Budget Negotiations
- Sponsor sends study protocol, proposed budget, CTA
- CMCT prepares proposed budget and sends to sponsor
- Final budget negotiated with sponsor

#### 11-23 Regulatory Docs Complete & Submitted
- 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

#### 24-26 Contract Complete
- 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

#### 27-29 Internal Billing accts set up
- 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

#### 30 Study Set-up
- Clinical trial begins (ESTIMATED DATE)
- 10/8/2010
- 10/8/2010
- Dr. Wei signed
- Dr. Wei signed
- 10/14/2010
- 2/7/2011
- 2/7/2011

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### Key individual assignments tracked

**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):**
- Initial responsibilities:
  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):**
- Initial responsibilities:
  1) Study team protocol evaluation
  2) Monitor visit
  3) Budget sign off
  4) Assist with IRB submission

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

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**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)
Historically what has been the Case success of going from This

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<th>Completion Date</th>
<th>Notes</th>
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<td>2</td>
<td>CDA/NDA sent to CTO</td>
<td>10/8/2010</td>
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<tr>
<td>3</td>
<td>CTO makes corrections</td>
<td>Dr. Wei signed</td>
</tr>
<tr>
<td>4</td>
<td>CMCT and sponsor sign CDA</td>
<td>N/A</td>
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<tr>
<td>5</td>
<td>Initial site selection</td>
<td>10/14/2010</td>
</tr>
<tr>
<td>6</td>
<td>Site questionnaire completed</td>
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<tr>
<td>7</td>
<td>Pre-study site visit</td>
<td>2/7/2011</td>
</tr>
<tr>
<td>8</td>
<td>Sponsor approves site selection</td>
<td>2/7/2011</td>
</tr>
<tr>
<td>9</td>
<td>Sponsor sends study protocol, proposed budget, CTA</td>
<td>2/7/2011</td>
</tr>
<tr>
<td>10</td>
<td>CMCT prepares proposed budget and sends to sponsor</td>
<td>Negotiation</td>
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<td>11</td>
<td>Final budget negotiated with sponsor</td>
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<td>12</td>
<td>Lay Language Protocol Summary</td>
<td>2/7/2011</td>
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<tr>
<td>13</td>
<td>Consent and HIPAA Auth. forms completed</td>
<td>2/7/2011</td>
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<tr>
<td>14</td>
<td>Clinical billing schedule completed</td>
<td>2/7/2011</td>
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<tr>
<td>15</td>
<td>IRQ completed</td>
<td>2/7/2011</td>
</tr>
<tr>
<td>16</td>
<td>Any additional forms required completed</td>
<td>2/7/2011</td>
</tr>
<tr>
<td>17</td>
<td>CMCT submits to IRB</td>
<td>2/7/2011</td>
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<tr>
<td>18</td>
<td>CMCT sends contract to CTO</td>
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<tr>
<td>19</td>
<td>Sponsor regulatory documents completed</td>
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<tr>
<td>20</td>
<td>Sponsor submits clearing of IRB</td>
<td>2/7/2011</td>
</tr>
<tr>
<td>21</td>
<td>Sponsor and OHSU sign final contract</td>
<td>2/7/2011</td>
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<tr>
<td>22</td>
<td>Internal OHSU accounts set up</td>
<td>2/7/2011</td>
</tr>
<tr>
<td>23</td>
<td>Research rate account set up</td>
<td>2/7/2011</td>
</tr>
<tr>
<td>24</td>
<td>Clinical trial begins (ESTIMATED DATE)</td>
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</table>

Cumulative revenues to date: 3.87 million
Applying Key Business Standards to the Production Model
### Regulatory Building

**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.
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
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 **One-Contact** 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.
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?
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.

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%.

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


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

Recruiting Plan Data:
- 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?

MEET AS A GROUP
Make your plan formal!

And this is a great Relationship Tool!
Getting the Bills Paid
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.
You need someone trained and experienced in business to run a business.
### Subject Data Set List

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<thead>
<tr>
<th>Subject Initials</th>
<th>Subject Number</th>
<th>Screening/Enrollment</th>
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<th>ACCRUED</th>
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<td>E-A</td>
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**Financial report as of 9/30/2011**

| SUBJECTS ENROLLED: 60 |

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<th>REVENUE</th>
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<td>Subtotal Other</td>
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<td>Patient stopped Plavix</td>
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<td>2001-01-06</td>
<td>Exit study d/t 2nd repeat PCI</td>
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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

CASH IS KING!!
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?