



Dedicated to your information and advancement.

Who's Doing What?

**Best Practices for Clearly Defining Roles,
Responsibilities, and Expectations**

Biotechnology Clinical Trials Outsourcing: 20 March 2009

Discussion Panel

Marianne R. Plaunt, Ph.D.
Vice President, Global Operations



Todd Reul
Associate Director, Clinical
Outsourcing



Kathy Feldkircher, PhD, MA
Sr. Director, Clinical Operations



Kenneth Wilson
Sr. Director, Business Development



Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to Drug Information Association, Inc. (“DIA”), its directors, officers, employees, volunteers, members, chapters, councils, Special Interest Area Communities or affiliates, or any organization with which the presenter is employed or affiliated.

These PowerPoint slides are the intellectual property of the individual presenter and are protected under the copyright laws of the United States of America and other countries. Used by permission. All rights reserved. Drug Information Association, DIA and DIA logo are registered trademarks or trademarks of Drug Information Association Inc. All other trademarks are the property of their respective owners.

Session Objective: Enabling Success

- How to work best with the provider you have chosen and to position your service providers for success?
 - Define work specifications
 - Establish roles and responsibilities
 - Define hand-offs between groups through the use of process maps
 - Effectively share and manage expectations



How the customer explained it



How the Project Manager understood it



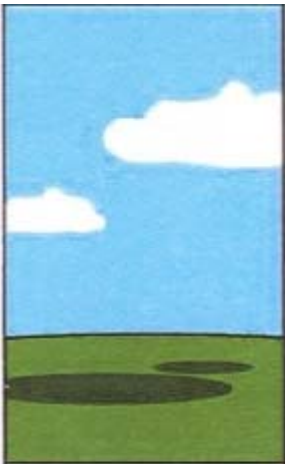
How the Designer designed it



How the Cadd Operator drafted it



How the Salesman described it



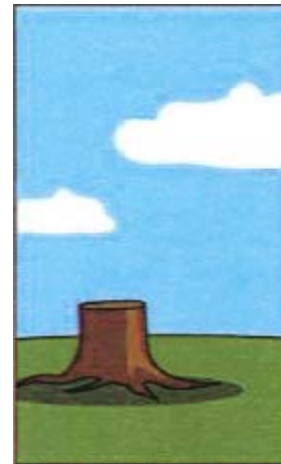
How the project was documented



What construction installed



How the customer was billed



The warranty that was offered



What the customer really wanted

Defining Work Specifications



Informal SP Contracting

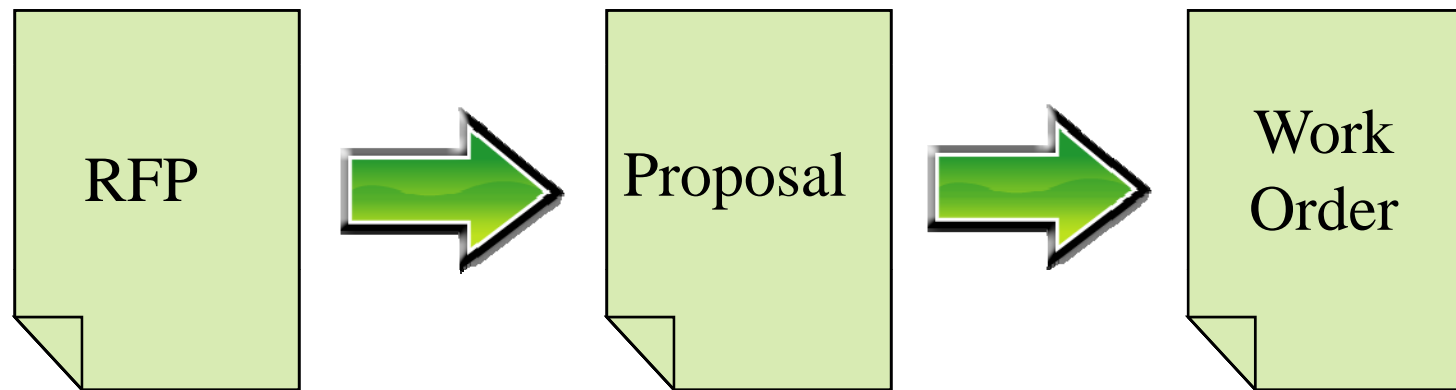
- Ad-hoc contracts (LOI's, SOWs, Start-Up Agreements, Emails, handshakes, winks, etc)



Disciplined SP Contracting

- Standard process
- Templates
- Defined responsibilities, budget and terms

Document Flow



Use the Responsibility Grid throughout
all steps of contract development

Case Study

- CRA just assigned to an ongoing project.
The team asks....**Where's the data?**
 - Investigation begins
- Work Order states...
 - “A Data Transfer will be provided to Sponsor containing patient data”
 - \$3,000 each

Responsibility Grid

Task / Activity	Sponsor	CRO	Suppliers	Comments
Q. Database Transfers				
Q1: Standard export format – Patient Data		X		
Q2: Test data transfer		X		
Q3: Provide file structure/specifications for all transfers	X	X		
Q4: Interim analysis data transfer(s)		X		

Budget

Task / Activity	Unit	Number Of Units	Cost Per Unit	Total Cost	Comments
Data Management					
Export data	Transfer	2	\$3,000	\$6,000	Interim data transfer

Case Study

- Needs more detail
 - What “patient data”?
 - When is it sent?
 - What frequency will the data be sent?
 - What data format?
 - Is there anything Sponsor needs to do?

Responsibility Grid

Task / Activity	Sponsor	CRO	Suppliers	Comments
Q. Database Transfers				
Q1: Standard export format – Patient Data		X		SAS datasets
Q2: Test data transfer		X		One test transfer will be provided for sponsor approval. Data Transfer will be ready no more than 2 weeks post-approval
Q3: Provide file structure/specifications for all transfers	X	X		Per DT Specifications. SP will provide sponsor with DT Specs, defining file structure/content. DT will include all patient demographic data and blinded per visit CRF information.
Q4: Interim analysis data transfer(s)		X		Two interim DT are needed after complete enrollment of Cohort 1 and 2

Budget

Task / Activity	Unit	Number Of Units	Cost Per Unit	Total Cost	Comments
Data Management					
Export data	Transfer	2	\$3,000	\$6,000	Interim data transfer

Budget

R-Grid Reference	Task / Activity	Unit	Number Of Units	Cost Per Unit	Total Cost	Comments
P.	Data Management					
P1, P2	Database Management	Per month	24	\$1,000	\$24,000	Ongoing maintenance to the database

Responsibility Grid

Task / Activity	Sponsor	CRO	Suppliers	Comments
P. Data Management				
P1: Status Reporting		X		Will assign a Data Management Lead to manage the data processing and status reporting and will provide a Data Management Programmer to perform database maintenance during study conduct
P2: On-Going Maintenance		X		

Roles and Responsibilities

- Coming together is a beginning.
Keeping together is progress.
Working together is success.
~ Henry Ford
- The whole is greater than the sum of its parts.

Roles and Responsibilities

- **CRO Responsibility/Sponsor?**
- **Medical Writing Case Study:**
 - Global Sponsor and Study
 - Study stopped ahead of schedule due to poor enrollment
 - 911 Rescue (2nd CRO assigned to complete study)

Roles and Responsibilities

- **Final Study Report Template ?**
- **Manuscript content ?**
- **Deadlines ?**
- **Publications?**

Responsibility Grid

Task/Activity	Sponsor	CRO	Suppliers	Comments
S. Medical Writing				
S.1 Provide draft study report(s)		X		
S.2 Review draft study report(s)	X	X		
S.3 Provide final study report(s)		X		
S.4 Approve study report(s)	X			
S.5 Retain final electronic data	X	X		
S.6 Retain final electronic study reports	X	X		



Sharing and Managing Expectations

Define

Refine

Share

Manage

“Understanding expectations from each other is a key element in defining success in any relationship”



Defining Expectations

- Expectations at different levels
 - Executive
 - On time
 - On budget
 - Quality
 - Team members
 - Detailed responsibility grid
 - Tasks within a timeline
 - Budget details
 - Quality

Case Study – Clinical Monitoring

Task / Activity	Sponsor	CRO	Suppliers	Comments
I. On-Site Monitoring				
I.1 Conduct interim on-site monitoring visits		X		
I.2 Review and verification of 100% of available source documentation on 100% of all data points in the CRFs		X		
I.3 Review drug records and patient accountability		X		
I.4 Verify investigators' compliance with protocol and regulatory requirements		X		
I.5 Obtain corrections to CRFs/query resolution		X		
I.6 Maintain site training of personnel		X		
I.7 Provide written site monitoring reports within "30" working days	X	X		Report to central files within 30 calendar days

Case Study

- Ongoing criticism:
“Monitoring reports are consistently late and often of poor quality”
- Is this statement perception or reality?

What are the expectations?

- Task durations
 - Draft trip report
 - Comments on report
 - Final report
 - Final report to central files
 - Qualitative metrics
- Who is responsible at each step?

Case Study Metrics

- Utilize summaries of metrics to manage expectations
- Other metrics to assist in managing expectations
 - Overall timeline tracking
 - Budget management
 - Quality



Pulling it all together: Documentation

- RFP Materials
 - Proposal
 - Work Order
 - Responsibility Grid
 - Project Plan(s)
 - SOPs, Guidelines, Work Instructions
 - Process Maps
- 



Thank You

- Additional questions or comments?

