Developing a Sponsor Global Strategy and How it Impacts Research Institutions: A Collaborative Interactive Discussion

Focus: Patient Recruitment

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Agenda

Objective

What is a Sponsor?

Sponsor's Role

Institution's Role

Questions

Objectives

- Be knowable of how a Sponsor's Global Strategies are developed including the following:
  - How vendors are selected
  - The types of services that were contracted
    - In the past
    - Current and future looking
  - How to request additional support
- Be knowable of how Institutional contracts and budgets are developed and executed

Clinical Research Studies

- ***Sponsor***
  - A “person or entity who takes responsibility for and initiates a clinical investigation. A sponsor may be an **individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization**.
  - The sponsor does not actually have conduct the investigation (Delegation of Authority) unless the sponsor is a sponsor-investigator (IIS)”
    - We will be reviewing **Sponsor-Initiated Studies**

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.3

Phases of Research Studies

Phase I Study
The Sponsor of the study tests an experimental drug or treatment on a small group of people (sometimes healthily volunteers) for the first time. The researchers evaluate the treatment's safety, determine a safe dosage range, and identify side effects.

Phase II Study
The experimental drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.

Phase III trials
The experimental study drug or treatment is given to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

Phase IV trials
Post-marketing studies, which are conducted after a treatment is approved for use by the FDA, provide additional information including the treatment or drug's risks, benefits, and best use.

https://www.fda.gov/ForPatients/ClinicalTrials/Types/ucm20041762.htm

Scope: Sponsor-Initiated

- In Scope : Clinical Research Pharmaceutical Trials- Phase 1-3

- Out of Scope: Non-Interventional, PMOS, PASS, PAES, registries, retrospective chart review and database analysis & non-drug interventional studies

Sponsor Strategic Vision to Contracting with Institutions

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Corporate Research Strategy Development

Start contracting with Selected Vendors that will provide services to for each study

Institution contracting to perform research studies

Strategy Development & Negotiation Process

Start contracting with Selected Vendor who will be providing services for each study

BPO

RFP Process

Sourcing Strategy

MSA
- SOWs (with Vendors)

Governance
- Policies

Institutional contracting for research studies <u>after</u> SOWs with Vendors are executed

BPO= Business Process Owner
RFP = Request for Proposal
MSA = Master Services Agreement
SOW=Statement of Work

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RFI/RFP Process for requesting MSA/Service Agreement (SA)

*** The vendor identified through this process will be providing services to the Institution on behalf of the Sponsor**

1 — Needs Assessment :
- Analyze Gap Analysis
- Justify Business Need

2 — Landscape Analysis (LA) :
(Market Assessment)
Internal & External

3 — CDA & RFI :
1. Execute CDAs w/ top LA top scorers.
2. Send RFI to top vendors from LA
3. Schedule capabilities assessment(s) with RFI recipients & scores

4 — RFP :
1. Upon execution deploy RFP to vendors with an executed CDA. Assess & score

5 — Bidder's Conference:
Score and select top 2 RFP recipients for bidders conference

6 — MSA or SA :
Award top scorer awarded with MSA
(or in some cases pilot SA)

CDA= Confidential Agreement
RFI= Request for Information
RFP= Request for Proposal
MSA= Master Service Agreement
SA= Service Agreement

Patient Recruitment-Full Service

Site Selection/Strategy

Site/Patient - Geographic Heat Mapping

Investigator Database

Patient Database

Patient Retention & Compliance Strategies

General Site and/or Site Specific Patient Recruitment Plans

Creative Development

Branding

Web Site Development

Recruitment/Retention Materials

Translations

Advertising

In-House Media Production

In-House Media Buy

Direct Mail

Print Advertising (i.e., news)

TV / Radio

Ad Development & Production

Screening

Screener development

Call Center

Training/Site Support

Investigator Meeting Attendance &Training

IRB Submissions

Outreach

Patient Outreach

Physician Outreach

Physician Referral Program

Community Outreach

Pharmacy Outreach

Site Engagement/ Relationship Mgt

Advocacy Group Support

Focus Groups - Physician or Patient Interviews

Retention

Travel concierge, reimbursement

Patient stipends

- These are the services that an Institution may potentially access for their sponsored research study

Transforming Patient Recruitment & Retention in the Digital World

Data Solutions

Leveraging emerging data and technology solutions to enhance the patient and site identification process

AbbVie Clinical Trial Digital Presence

Establishing a robust global digital presence to:
- Increase awareness regarding AbbVie clinical trials with patients, HCPs, and investigator sites

Patient & Site Engagement

Supporting clinical trial patients, caregivers, and study sites with engaging, on-demand mobile clinical trial connectivity

TA & Program Specific Solutions

Enabling TA and Program specific solutions to meet the needs of the portfolio
- Providing capabilities for multi-media outreach campaigns for specific programs, as required

Patient Recruitment: Full & Specialty Service

Site Selection/Strategy

Site/Patient-Geographic Heat Mapping

Investigator Database

Patient Database

Patient Trial Matching

EMR-identified patients/sites

Patient Retention & Compliance Strategies

General Site and/or Site Specific

Patient Recruitment Plans

Creative Development

Branding

Web Site Development

Recruitment/Retention Materials

Translations

Advertising

In-House Media Buy

Direct Mail

Print Advertising (i.e., news)

TV / Radio

Ad Development & Production (Social Listening)

Screening

Screener development

Call Center

Training/Site Support

Investigator Meeting Attendance &Training

IRB Submissions

On-site enrollment assistance, chart review

Outreach

Patient Outreach

Physician Outreach

Physician Referral Program

Community Outreach

Pharmacy Outreach

Site Engagement/ Relationship Mgt

Advocacy Group Support

Focus Groups - Physician or Patient Interviews

Digital Outreach

Retention

Travel concierge, reimbursement

Patient stipends

Patient Engagement/Insight Capture Apps

* These are the refined services that an Institution may potentially access for their sponsored research study

Orange = Decreased service offerings
Green = Increased or added services offerings

Institutional Role

Intuitional Perspective of Sponsor Research Studies

Study Operations and Management

Contracting for Studies

Maintenance and Retention Tactics of Subjects

How can we partner better together?

Study Operations and Management
Institutional Vetting Process for Clinical Trials

- Feasibility Questionnaire
- Does the Institution have other Competing Trials?
- Does the Institution have the necessary Facilities to full-fill the requirements of the Trial?
- Are there other investigational therapies at the Institution that can be offered to this particular Patient Population?

Sponsored Research Studies: Institution's Role

PI Interested in Study

Regulatory, Contracting, Full Budget Preparation Begin

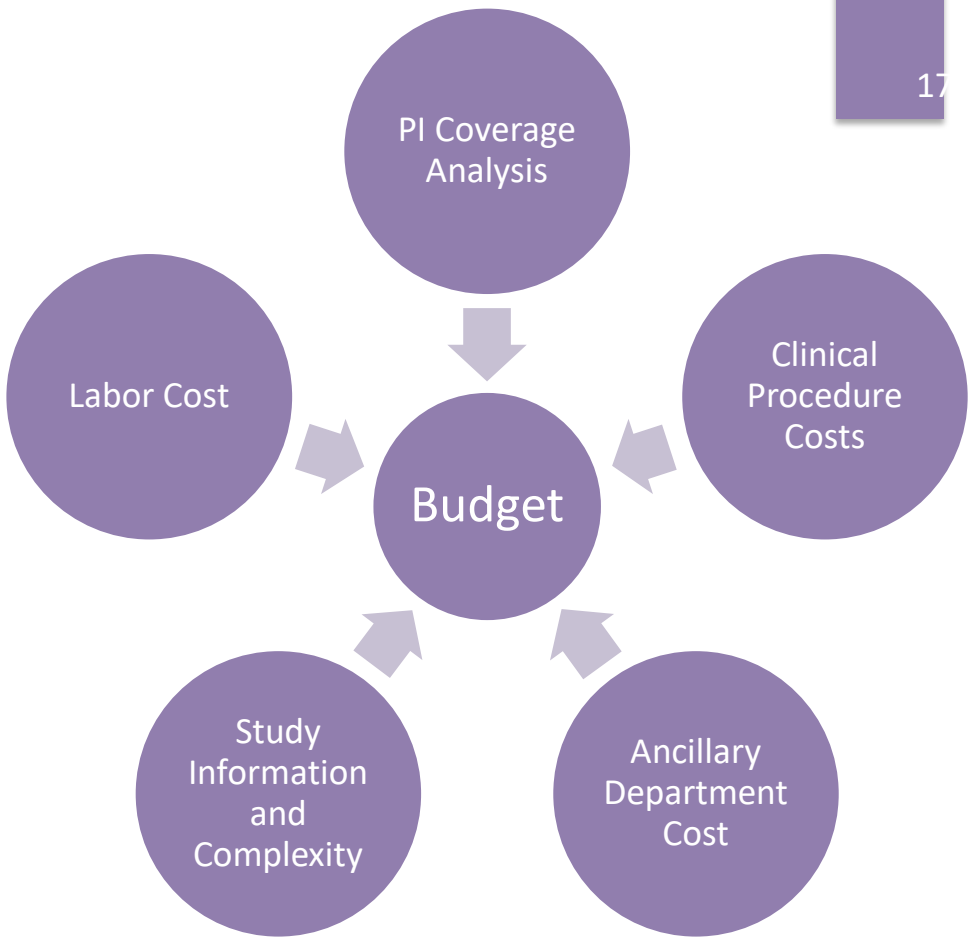
Agreements Finalized

Sponsor Review and Approval of Administrative Fees

Study Reviewed by Departments, Begin Negotiations

Open Study at Site

Budget Review Process



Example Budget

Investigator:	Doctor T.
Protocol #:	
Protocol Version & Date:	4/30/2019
Title:	A Phase II.....
Sponsor:	Abbvie
Project Period (in Years):	3
Drug Provided:	[STUDY DRUG]
Budgeted # of PTS:	10
Per Patient Payment	$ 10,348.00

CPT	Billed By:	Per Patient Procedures	Rate	Screening	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	End of Treatment	Follow Up	Sub-Totals
	CTO	Clinical Research Coordinator Fee	$ 125.00	$ 500.00	$ 250.00	$ 250.00	$ 250.00	$ 500.00	$ 250.00	$ 500.00	$ 125.00	$ 2,625.00
	CTO	Data Manager	$ 85.00	$ 340.00	$ 170.00	$ 170.00	$ 170.00	$ 340.00	$ 170.00	$ 340.00	$ 85.00	$ 1,785.00
	PI Dept.	Investigator Fee	$ 100.00	$ 200.00	$ 200.00	$ 100.00	$ 100.00	$ 100.00	$ 100.00	$ 200.00	$ 100.00	$ 1,100.00
		Informed Consent	SOC	X								$ -
		Inclusion/Exclusion	SOC	X								$ -
		Medical History	SOC	X								$ -
93005	NMH/NMG	12 Lead ECG - Triplicate	$ 400.00	$ 400.00		$ 400.00		$ 400.00		$ 400.00		$ 1,600.00
		ECOG Performance Status	SOC	X	X	X	X	X	X			$ -
		Serum Chemistry Labs	SOC	X	X	X	X	X	X			$ -
84443, 844	NMH	Thyroid Function Test (TSH, Free T4, T3)	$ 50.00	$ 50.00						$ 50.00		$ 100.00
		Hematology	SOC	X								$ -
		Adverse Events	SOC	X	X	X	X	X	X	X	X	$ -
		Pregnancy Test	SOC	X								$ -
	NMH/NMG	CT or MRI Scan with Contrast	$ 2,500.00	Invoice				Invoice				$ -
	Imaging	RECIST	$ 200.00	$ 200.00				$ 200.00				$ 400.00
	PCF	Blood Collection for Lab Sendout	$ 100.00	$ 100.00								$ 100.00
		Study Drug Administration	SOC									$ -
	Pharmacy	Study Drug Dispensing Fee	$ 50.00		$ 50.00	$ 50.00	$ 50.00	$ 50.00	$ 50.00			$ 250.00
												$ -
												$ -
		Subtotal Per Patient		$ 1,790	$ 670	$ 970	$ 570	$ 1,590	$ 570	$ 1,490	$ 310	$ 7,960
		Overhead	30%	$ 537	$ 201	$ 291	$ 171	$ 477	$ 171	$ 447	$ 93	$ 2,388
		Total		**$ 2,327.00**	**$ 871.00**	**$ 1,261.00**	**$ 741.00**	**$ 2,067.00**	**$ 741.00**	**$ 1,937.00**	**$ 403.00**	**$ 10,348.00**

Initiation Fees	
Pathology Core Facility-Clinical Trials Unit (PCF-CTU)	$ 1,534.57
IRB (Exempt from Overhead)	$ 2,000.00
Pharmacy	$ 2,500.00
Clinical Trials Office (CTO)	$ 15,000.00
Total Initiation Fees	$ 21,034.57

Annual Fees	
Pathology Core Facility-Clinical Trials Unit (PCF-CTU)	$ 1,000.00
IRB (Exempt from Overhead)	$ 1,500.00
Pharmacy	$ 2,600.00
Clinical Trials Office (CTO)	$ 10,000.00
Total Annual Fees for 3 Year(s)	$ 15,100.00

Total Administrative Fees	**$ 36,134.57**
Study Total for 10 Patients	$ 139,614.57

Two years of annual fees
(3 year study)

Translating Internal Budget into Sponsor Template

Screening	Cycle 1	Cycle 2
$ 500.00	$ 250.00	$ 250.00
$ 340.00	$ 170.00	$ 170.00
$ 200.00	$ 200.00	$ 100.00
X		
X		
X		
$ 400.00		$ 400.00
X	X	X
X	X	X
$ 50.00		
X		
X	X	X
X		
Invoice		
$ 200.00		
$ 100.00		
	$ 50.00	$ 50.00
$ 1,790	$ 670	$ 970
$ 537	$ 201	$ 291
$ 2,327.00	**$ 871.00**	**$ 1,261.00**

Table 2 - Fees for Completed Clinical Visits for Randomized Subjects

VISIT	FEE
Screening	$2,327.00
Cycle 1	$871.00
Cycle 2	$1,261.00
Cycle 3	$741.00
Cycle 4	$2,067.00
Cycle 5*	$741.00
EOT/ET	$1,937.00
Follow Up	$403.00
TOTAL PER PATIENT	**$10,348.00**
Additional Follow Up	$403.00

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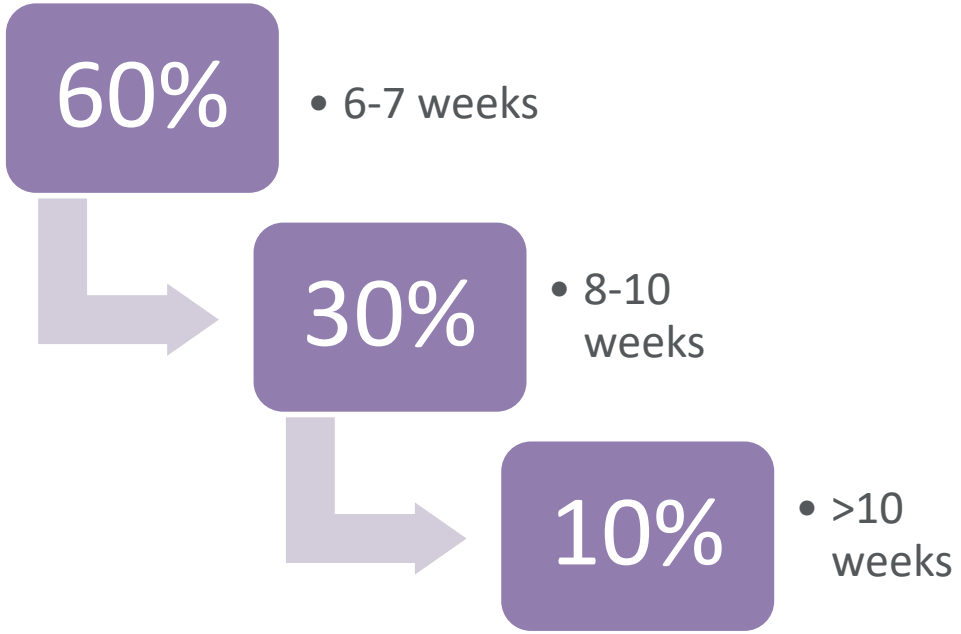
Additional Budget Aspects

- Payment Terms Negotiated
  - Timing of payments
  - Timing of EDC Entry
  - Holdback
- Invoiceable items
  - Contingent procedures
  - Screen Failures
  - Unscheduled Visits

Budget Timelines



Reasons for delay beyond 6-7 week period:

- Company delay
- Waiting on new amendment
- PI
- Ancillary Department delays

Common Issues

Industry Sponsored

- Administrative Site Fees
- Ancillary Department costs
- Biopsy Costs

Investigator Initiated

- Under funded or no funding
- New procedures not included in LOI budget
- Affiliate Site Admin Costs

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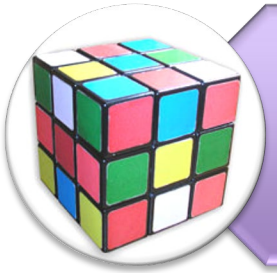
Contracting:
An Institutional Perspective

Contracting

Contracting Mechanisms



Challenges

Solutions

Common Contracting Mechanisms

CDA / NDA

- Confidentiality or Nondisclosure Agreement
- Enables initial sharing of protocol, study brochure, and information necessary for site PI to determine whether she wants to perform the study

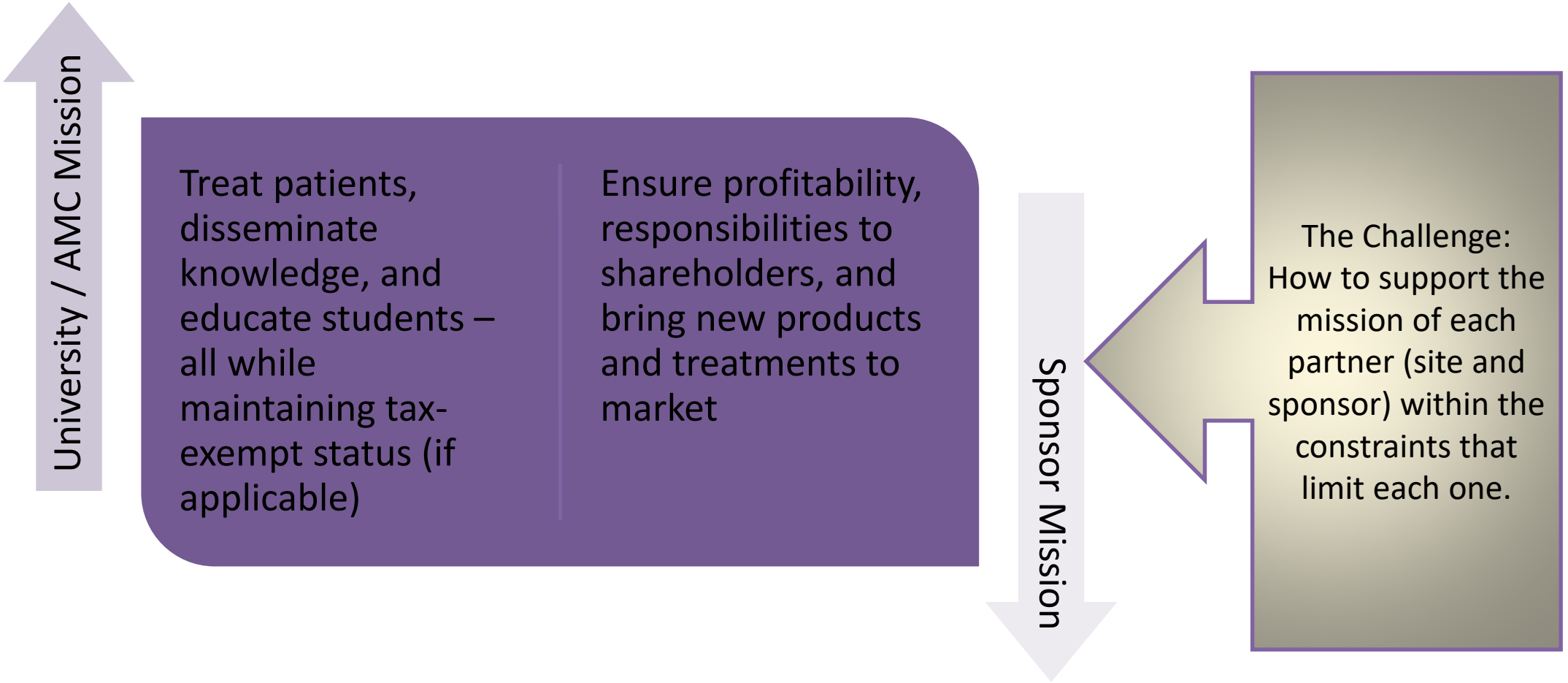
CTA

- Clinical Trial Agreement
- Between pharma or device company and Academic Medical Center (or health system, hospital)
- Sets terms under which site will conduct the trial

LOI

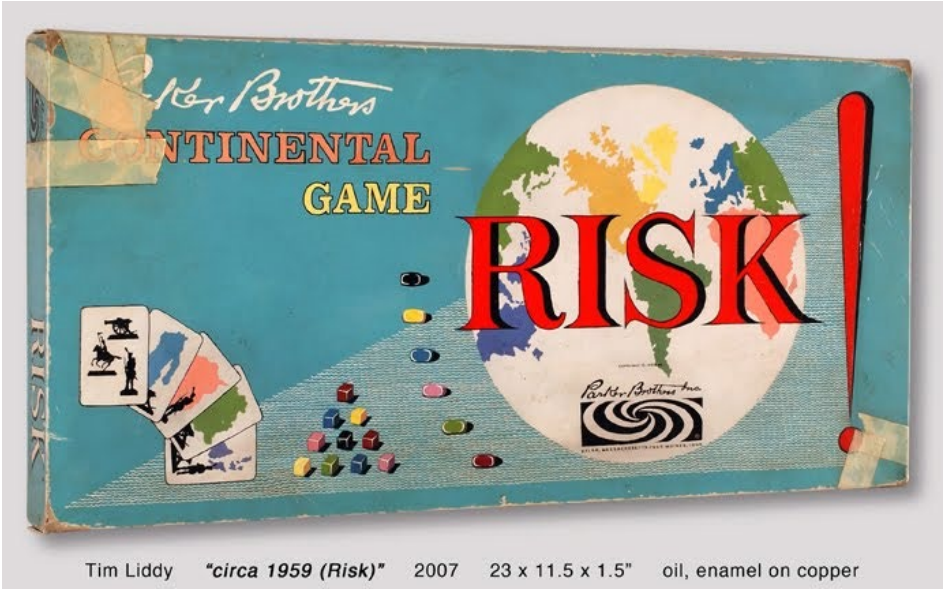
- Letter of ~~Intent~~ Indemnification
- Sites may require a separate LOI between pharma or device company and site if a CRO signs the CTA
- Establishes sponsor's indemnification, insurance, and subject injury commitments

CTA Challenges



CTA Challenges: Highlights

- **INDEMNIFICATION:**
  - Language in a contract where one party agrees to protect another against anticipated loss or damage.
  - Scope of indemnity?
  - Who is covered? (Site, Hospital, PI, IRB?)
  - What is the process?
  - Can the site indemnify the sponsor?
  - What about negligence of site or sponsor?
  - NOTE: Insurance should be able to support a party's indemnification obligations.



Tim Liddy *"circa 1959 (Risk)"* 2007 23 x 11.5 x 1.5" oil, enamel on copper

CTA Challenges: Highlights

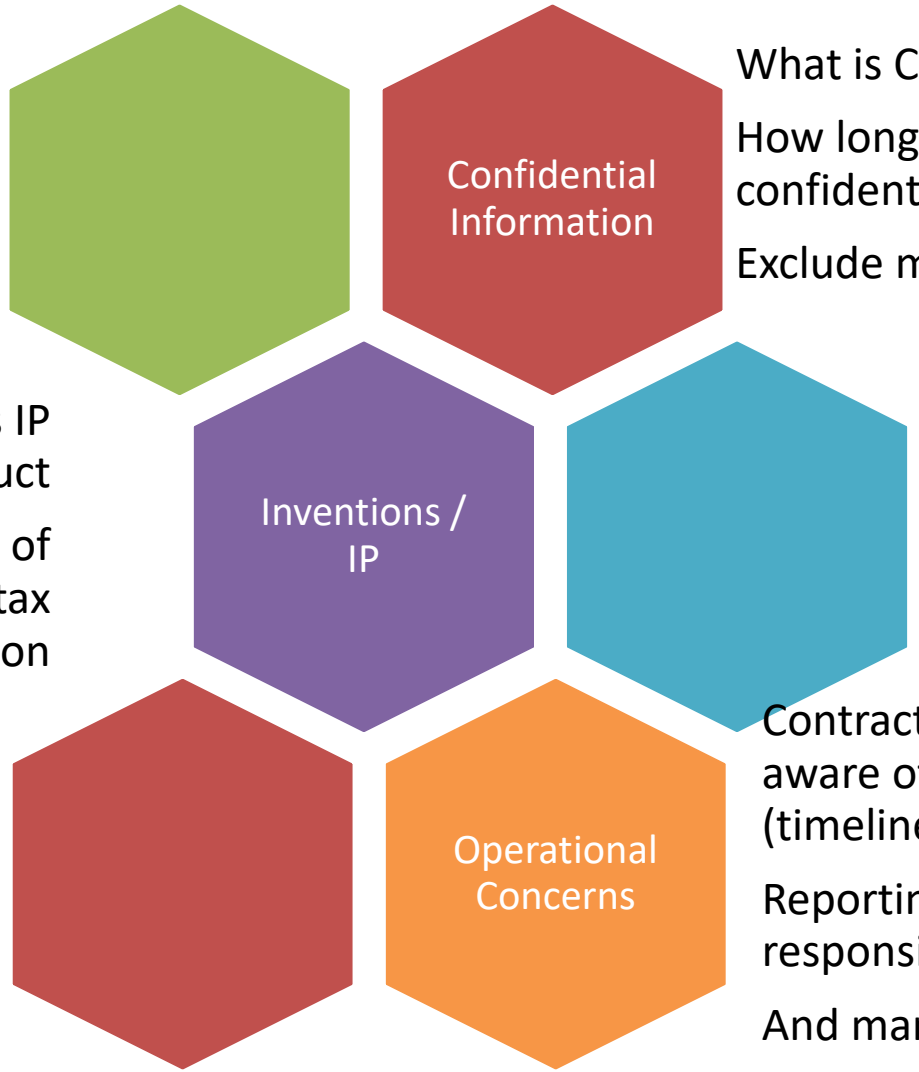
- **SUBJECT INJURY REIMBURSEMENT:**
  - Language in a contract where the sponsor agrees to reimburse expenses associated with diagnosing and treating injuries, complications or adverse events experienced by a subject as a result of or during participation in a clinical trial.
  - Who determines causation?
  - Bill insurance (many AMC's won't)?
  - What is the process?
  - What about longer-term care that might be required?
  - Other expenses not usually covered (lost wages, etc…)
  - NOTE: CTA language must be consistent with ICF.

CTA Challenges: Highlights

- **Publication & Data Usage:**
  - Language in a CTA authorizing the site to publish, present, and use data and results from the trial.
  - Most AMCs require these rights
  - Publications: Reasonable review/comment periods for sponsor
  - Data use: Internal, non-commercial educational and research purposes
  - Multi-center publications
  - Patent delays
  - NOTE: Societal interest in ensuring results of trials are made public.

ICMJE
INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

CTA Challenges: Highlights



What is Confidential Information?

How long do we have to maintain confidentiality?

Exclude medical records

Sponsor usually owns IP associated with study product

Site may require ownership of certain IP – depending on tax status and mission

Contracts negotiator needs to be aware of departmental / clinic needs (timelines, access, etc…)

Reporting mechanisms and responsibilities

And many other needs

Solutions

- **Communicate** (with sponsors; departments; investigators; study staff).
- **Understand** we are all working toward shared goals – improving treatment and health for patients (including ourselves).
- **Listen** more.

Solutions

Master CTAs

- Simplify contracting process
- Generally require high volume of contracts to justify effort required, but can save time

Template Agreements

- Similar in utility to master CTAs
- Working together repeatedly can enable the parties to re-purpose prior CTAs

Model Agreements

- **ACTA** (ara4us.org)
- **MAGI model agreement** (magiworld.org)
- **EFS Master** (Early Feasibility Device Trials: https://mdic.org/resource/efs-master-clinical-trial-agreement-mcta/)

Institutional Maintenance and Retention Tactics of Subjects

- Patient Recruitment:
  - Recruitment occurs during an initial visit with provider
  - Providers will discuss the study if deemed appropriate for the patient
  - Provider will discuss the patients interest in participating
  - If interested, the patient will be referred to the study team to be vetted.

Institutional Maintenance and Retention Tactics of Subjects

- On-boarding and Retention:
  - Patient is scheduled for a screening visit
  - Patient meets with Research Coordinator and/or Nurse to discuss details of the study
  - Patient is presented with necessary recruitment materials
  - If interested in continuing, Patient is consented prior to any screen testing
  - If applicable, testing is done to ensure the patient is eligible for the study
  - Research Coordinator and/or Research Nurse typically handle patient follow-ups as the patient progresses on study
  - Provider will monitor patient progression and have follow-up conversation during subsequent visits and/or calls

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Questions

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