How to Get Your Clinical Trial Agreement Finalized Faster

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It’s only a contract. So why does it take so long?
Presentation Components

- Highlight SPA statistics
- Identify common causes for delays
- Recommend strategies for reducing delays
- Introduce upcoming changes

Acronyms and Their Meaning

- CDA: Confidentiality Disclosure Agreement
- NDA: Non-Disclosure Agreement
- CTA: Clinical Trial Agreement
- CRO: Contract Research Organization
- COI: Conflict of Interest
- CRC: Clinical Research Center
- SRC: Scientific Review Committee
- ICF: Informed Consent Form
SPA Statistics

2.5  SPA contract negotiators FTE
78  SPA contracts finalized in FY10–11*
23  SPA agreement types

* excluding CDAs/NDAs
SPA Statistics (continued)

- **464**: Longest negotiation period*
- **13**: Shortest negotiation period*
- **54.5**: Average days in negotiation with master agreement in place (i.e., work order)
- **15**: SPA master agreements

* excluding CDAs/NDAs

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Masters: CTAs and CDAs

**MASTER CLINICAL TRIAL AGREEMENTS (CTAs)**
- **Existing**: Finalized
  - Pfizer
  - Pharmacyclics, Inc.
  - Philips Medical Systems MR, Inc.
  - Sanofi Aventis
  - Myrexis, Inc.

  **Pending**: Actively Negotiating
  - InterMune

**MASTER CONFIDENTIALITY AGREEMENTS (CDA)**
- Abbott
- Quintiles
- Siemens [to be negotiated]
SPA Agreement Types

- CDA/NDA
- Clinical Trial
- Material Transfer
- Master
- Work Order
- Registry
- Subcontract/Intra-institutional
- Testing/Research Services
- Research
- International
- Emergency Use
- C–GMP (Good Manufacturing)
- State of Nebraska
  - Federal flow through
  - Non–federal
- Data Use
- Core Facility
- Cooperative
- Subcontracts
- Other

SPA Negotiations: Average Days Fiscal Year 2010–11*

- **111** All agreement types
- **143** With CRO involved
- **97** Without CRO involved

* excluding CDAs/NDAs
SPA Negotiations: Average Days Fiscal Year 2010–11*

71 Phase 1 Clinical Trial Agreement
125 Phase 2 Clinical Trial Agreement
143 Phase 3 Clinical Trial Agreement
168 Phase 4 Clinical Trial Agreement
* excluding CDAs/NDAs

Expertise in Contract Negotiations

› SPA brings expertise to contract negotiations

› Our practices match standards for academic/commercial sponsor agreements

› Our goal is to . . . establish long-term relationships with our customers (i.e., you)

› . . .and with your sponsor
SPA Contract Specialists

› Barbara Mattson, M.P.A., Contracts Specialist
  • Education
    • Bachelor of Science in Biology, minor in Chemistry
    • Master of Public Administration
    • Completion of 72 hours towards Juris Doctorate
  • Relevant experience
    • Intellectual Property Licensing and Business Development
    • Legislative issues analysis and management
    • 8 years as a Research Technologist at UNMC
    • 7 years experience in SPA contract negotiation

SPA Contract Specialists

› Kara Schmidt, M.P.A., Contracts Specialist
  • Education
    • Bachelor of Arts in Sociology
    • Master of Public Administration
  • Relevant experience
    • 7 years in SPA as specialist
    • Administering grants and contracts
    • 6 years SPA contract negotiation experience
SPA Contract Specialists

- **Tara Scrogin, J.D., Contracts Specialist**

  - **Education**
    - Bachelor of Science in Biology, with Chemistry and Psychology minors
    - Juris Doctorate

  - **Relevant experience**
    - Molecular biology research
    - Medical negligence defense litigation
    - Special investigations for an insurance company
    - 3 years experience in SPA contract negotiations

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**Common Causes of Delays**
Common Causes of Delays

Delays can result WHEN . . .

- Your CTA includes sub-sites (i.e., subcontracts)
- You are providing a CRO function
- You are conducting a device study
- Study sponsor is under a corporate integrity agreement
- Sponsor is working through a CRO
- Your study requires a COI Management Plan
- Sponsor doesn’t understand the UNMC/TNMC/UNMC-P structure

Strategies to Avoid Delays
Strategies

- Determine if study is a “right fit” before moving forward
  - Consider availability of subjects, staff, space, time, $.

- If study is complex, consider meeting with SPA early in the process
  - e.g. multiple sites, a device study, CRO function.

- If you have concerns, communicate them to us via phone, email or one-on-one
  - Some studies are creating first-time experiences for the PI, coordinators, and SPA.
  - Learning together has advantages.
    - “None of us is as smart as all of us”.

Strategies (continued)

- Become familiar with the SPA process
  - SPA uses first-come, first-serve and prioritization.
  - SPA consults with multiple UNMC offices.
    - Compliance Office
    - Legal Counsel
    - IRB
    - Risk Management
    - More . . .

- Look for study events that involve TNMC
  - TNMC wants to understand the true cost of research.
  - TNMC wants to participate in managing risk.
Strategies (continued)

- If you have several contracts under negotiation, prioritize the order in which they should be negotiated—and let SPA staff know.
- If you change your mind about a study and no longer want to participate, remember SPA staff need to know, too.
  - This action maximizes limited resources.
- Understand the differing perspectives held by the sponsor vs. SPA.

Three Players. Three Perspectives.

**Sponsor**

- **Principal Investigator**

  - **Feasibility assessment**
  - **Population**
  - **Resources**
  - **Risk**
  - **Timelines**
  - **Cost**

  **SPA Contract Negotiation**
  - **<100 days = UNMC Target**

  **Clock Starts**
  - **SPA DEFINITION = Day contract package received in SPA**

  **Clock Stops**
  - **SPA DEFINITION = Day contract is fully-executed**

  **Clock Starts**
  - **SPONSOR DEFINITION = Day materials sent to department**

  **Clock Stops**
  - **SPONSOR DEFINITION = Day of first subject enrollment**
Upcoming Changes

Recent Clinical Research Initiatives

- Development of Master Agreements
- Active collaboration between VCR office and SPA
- Creation of Assistant Vice Chancellor for Clinical Research
- Renovation of CRC
- Preparation for EPIC
- Establishment of Advisory Board(s)
- Implementation of Strategic Planning Goal
  - <100 days
- Continuation as Quintiles Prime Site
Take Home Tips

**Tips**

- SPA negotiations do not begin until SPA has key components:
  - Sponsor’s contract template in editable form
    - i.e., Word document
  - Sponsor’s point of contact for legal negotiations
    - Name and contact info
  - SPA Contract Questionnaire
    - Form available on SPA web page

- SPA’s automated system (via ADIS) is designed to increase efficiencies
  - Ensures required documents (i.e., key components) have been sent and received
**Tips**

- Contract negotiation can take place in parallel with:
  - Regulatory reviews [IRB and SCR]
  - Negotiation of the budget [Department]
  - Submission of COI Disclosures

- Contacts at the company can be valuable
  - PI contacts have helped move stalled contracts

- Staying in touch with SPA may improve outcomes
  - Keep us informed of budget negotiations and status of COI, IRB and/or SRC approvals

**Contact Us**

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Questions

Click below for a script of the October 13, 2011 Q&A.
http://www.unmc.edu/media/spa/october_2011_learn_at_lunch Presentation Qas.pdf