Standardization/Harmonization of Clinical Trial Agreement Terms

Dr. James H. Doroshow
Director, NCI Division of Cancer Treatment and Diagnosis

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Project Rationale

• Negotiation of clinical trial agreements between industry and academic medical centers is one of the key barriers to timely initiation of cancer clinical trials.

• Perception: negotiated agreements contain clauses reflecting common key agreement concepts.

• Perception: reaching common ground for each agreement requires unnecessary duplication of effort that delays trial initiation.
Motivating Events

- **NCI Clinical Trials Working Group**
  - Recommended establishing commonly accepted clauses for clinical trial agreements between industry and academic medical centers

- **CEO Roundtable on Cancer Life Sciences Consortium**
  - Identified standardization of key clinical trial agreement clauses as a top priority

- NCI and CEO-RT established partnership to achieve common language
Participants

- **Life Sciences Consortium Companies**
  - AstraZeneca
  - Eli Lilly
  - GlaxoSmithKline
  - Johnson & Johnson
  - Novartis
  - OSI Pharmaceuticals
  - Pfizer
  - Quintiles
  - Sanofi-Aventis
  - Schering Plough
  - Wyeth
Participants

- NCI-Designated Cancer Centers
  - U. of Arizona
  - City of Hope
  - U. of Chicago
  - U. of Colorado
  - Dana Farber
  - Fox Chase
  - Johns Hopkins
  - Mayo Clinic
  - Moffitt
  - MD Anderson
  - U. of Pittsburgh
  - Roswell Park
  - UNC Lineberger
  - UCSF
Participants

• Cooperative Groups
  – Eastern Cooperative Oncology Group
  – Southwest Oncology Group
  – Cancer and Leukemia Group B
  – Gynecologic Oncology Group
  – Children's Oncology Group
Project Goals

• Identify key clauses that delay or complicate negotiations

• Determine if perception is correct that negotiations lead to consistent key concepts for those clauses

• **Draft proposed language for common key concepts identified**

• Obtain input from participants on language
Project Structure

- **Involved legal and business representatives from participants**
  - 17 reps. from LSC companies
  - 26 reps. from NCI-Designated Cancer Centers

- **Obtained copies of 78 clinical trial agreements from participating organizations**
  - 49 redacted copies of final negotiated agreements
  - 29 agreement templates
    - Approximately equal numbers of agreements from LSC companies and Cancer Centers
    - Agreements included company-sponsored and investigator-initiated trials
Key Clauses

• Through discussions with legal and business representatives, identified:
  – Intellectual property
  – Study data
  – Publication rights
  – Subject injury
  – Confidentiality
  – Indemnification
  – Biological samples
Agreement Analysis

- Identified **45 key concepts** in the 7 clause categories
- Captured **exact language** that embodied these concepts for all 78 agreements
- Organized agreement language into categories representing embodied concept
- Analyzed results for similarities and differences in key concepts across final negotiated agreements
- Analyzed **template agreements** for key differences with negotiated agreements
Agreement Analysis Results

- Final negotiated agreements showed greater than 67% convergence on the vast majority of concepts analyzed
- **Drafted proposed clauses** based on common concepts identified
- **Obtained input** on proposed clauses from legal and business **participants**
- **Refined proposed clauses** based on feedback
### Intellectual Property

**Company-Sponsored Trials**
- Inventions owned by company
- Research institution retains right to use inventions for non-commercial research and education

**Investigator-Initiated Trials**
- Inventions owned by research institution
- Research institution grants company a royalty-free, non-exclusive license and an option to obtain a royalty-bearing exclusive license
Study Data

• **Company-Sponsored Trials**
  - Research institution owns medical records
  - Company owns study data records and reports
  - Research institution makes medical records available to company (for study monitoring) and to regulatory authorities
  - Company licenses research institution to use study data for non-commercial research and education purposes (subject to confidentiality) and for publications
Study Data (cont’d)

• **Investigator-Initiated Trials**
  – Research institution owns medical records and study data
  – Research institution makes medical records available to regulatory authorities
  – Research institution makes study data available to regulatory authorities and company
Publication Rights

- **Company-Sponsored Trials**
  - Research institution can publish study data after 30-day company review period
  - Company right to require removal of company confidential information other than study data
  - Company right to delay publication for additional 60 days to apply for patents on inventions
  - Individual sites in multi-site studies may publish after a multi-site publication or 18 months after completion, termination or abandonment of the study, whichever is earlier
Publication Rights (cont’d)

- **Investigator-Initiated Trials**
  - Research institution can publish study data after 30-day company review period
  - Company right to require removal of company confidential information
  - Company right to delay publication for additional 60 days to apply for patents on inventions
Subject Injury

- **Company-Sponsored Trials**
  - Company reimburses research institution for treatment of adverse events and personal injury resulting from study
  - Except if caused by research Institution negligence or failure to follow protocol/applicable law

- **Investigator-Initiated Trials**
  - Subject injury reimbursement provisions not included in 90% of negotiated investigator-initiated agreements
Confidentiality

• **Company-Sponsored Trials**
  – Company pre-existing information and intellectual property, the protocol and study data are company confidential information
  – Research institution protects company’s confidential information during the study and for 5 years after
  – Research institution can publish study data in accordance with the publication provision

• **Investigator-Initiated Trials**
  – Company pre-existing information and intellectual property is company confidential information
  – Research institution protects company’s confidential information during the study and for 5 years after
Antitrust Considerations

• **Request for a Business Review Letter (BRL) from the Department of Justice (DOJ) Antitrust Division**
  – Favorable response received in early September
  – BRL indicated that DOJ has reviewed project and has no present intention to challenge the initiative

• **Implementation requirements include:**
  – Standardized/harmonized clauses are intended only as a starting point for individual negotiations between the parties
  – No agreement or understanding among project participants to use any of the standardized/harmonized clauses in their agreements
  – Companies and clinical centers should not discuss:
    ▪ Strategies in negotiating clinical trial agreements
    ▪ Specific language they will use in any particular contract
    ▪ Other competitively sensitive terms or issues
Next Steps

• **Cancer Centers**
  – Presentation of *proposed clauses for common concepts* to Cancer Center Directors
  – Discussion with legal and business representatives of Cancer Centers not participating in initial project
  – NCI *requests* Cancer Centers to make their home institutions aware of the *proposed clauses for common concepts*
  – NCI *discusses project with academic medical centers*
Next Steps

• **Company Sponsors**
  
  – LSC member companies *individually* decide whether to adopt *common concepts* as their starting point for negotiations
  
  – Discuss *proposed clauses for common concepts* with sponsors of cancer clinical trials that are not LSC members
  
  – Publicize the *project and proposed clauses for common concepts* through professional and trade associations, industry meetings and other opportunities
Appreciation

• Tech Transfer and Legal Staffs from Academic Medical Centers, Cancer Centers, Cooperative Groups, and Pharmaceutical Firms

• Drs. Judy Hautala, Dale Shoemaker, and Sheila Prindiville: STPI and NCI

• Hogan & Hartson