Clinical Trial Agreements

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Objectives

- Contract Requirements
- Common Contracts & Agreements
- Key Roles & Responsibilities
- Negotiations
- Investigator Perspective

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Contract Requirements

- Good Clinical Practice 1.17 Contract:

  A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

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Contract Requirements

GCP	Contract/Agreement	Investigator / Site Files	Sponsor Files
8.2.4	**Financial Aspects of Trial** To document financial agreement between Site and Sponsor	Yes	Yes
8.2.5	**Insurance Statement** To document that compensation to subject(s) for trial-related injury will be available	Yes	Yes
8.2.6	**Signed Agreements between** Involved Parties To document agreements	Yes	Yes

Legal Entity & Signing Authority

- Legal Entity
  - Determine legal entity of sponsor, Investigator centre, Institution
  - NCIC CTG legal entity is Queens University
- Signing Authority
  - Determine who is authorized to sign
  - NCIC CTG signatory is Director of Queens Office of Research Services and NCIC CTG Group Director

Common NCIC CTG Contracts & Agreements

- Bilateral Confidential Disclosure and Limited Use Agreement
  - Agreement between sponsor and company
  - Signatories intend to hold discussions and exchange information

Common NCIC CTG Contracts & Agreements

- Participating Centre Agreement (PCA)
  - Agreement between sponsor and Investigator centre
  - Signatories intend to conduct a clinical research and responsibilities are specified
  - NCIC CTG has PCA with each Investigator centre that covers all research conducted; Renewable every 5 years
  - If Trial Specific PCAs are required this can cause delays in trial activation and accrual

Common NCIC CTG Contracts & Agreements

- Tumor Tissue Data Repository (TTDR), Clinical Trial Tissue Access Agreement
  - Agreement between sponsor and Investigator
  - Contract to access trial specific clinical database held by NCIC CTG as well as tissue samples collected for the clinical trial
  - Investigator applies to NCIC CTG to conduct a research project related to the database/tissue and an agreement is signed

Common NCIC CTG Contracts & Agreements

- Data Sharing Agreement
  - Agreement between sponsor and Investigator
  - Results of a study have been published
  - Investigator applies to NCIC CTG to conduct additional research project on the database and an agreement is signed
  - NCIC CTG provides a partial anonymized database to the Investigator for the project

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Common NCIC CTG Contracts & Agreements

- Clinical Trials Agreement (CTA) and Collaboration Agreements
  - Agreement between sponsor and Intergroup partner
  - Signatories intend to conduct a clinical research study according to a protocol
  - Roles and Responsibilities are detailed

Key Roles & Responsibilities

- Protocol and protocol amendments
- Case Report Forms
- Informed Consent Form
- Investigational Medicinal Product
- Correspondence with Health Authorities
- Serious Adverse Event Reporting
- Safety Monitoring
- Research Ethics Board Approvals/Ethics
- Audit and Monitoring

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Key Roles & Responsibilities

- Site and Investigator Selection
- Trial and Investigator Centre Initiation
- Investigator Meetings
- Data Management
- Trial Close Out
- Statistical Analysis and Report
- Communication
- Other (ie Trial Master File retention)

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Contract Negotiations

- Communication
  - Legal team discussing aspects of trial conduct
- Roles and Responsibilities
  - Management of expectations
  - Agreement to timelines and deliverables
  - Discussion over on-site monitoring strategies and different costs associated

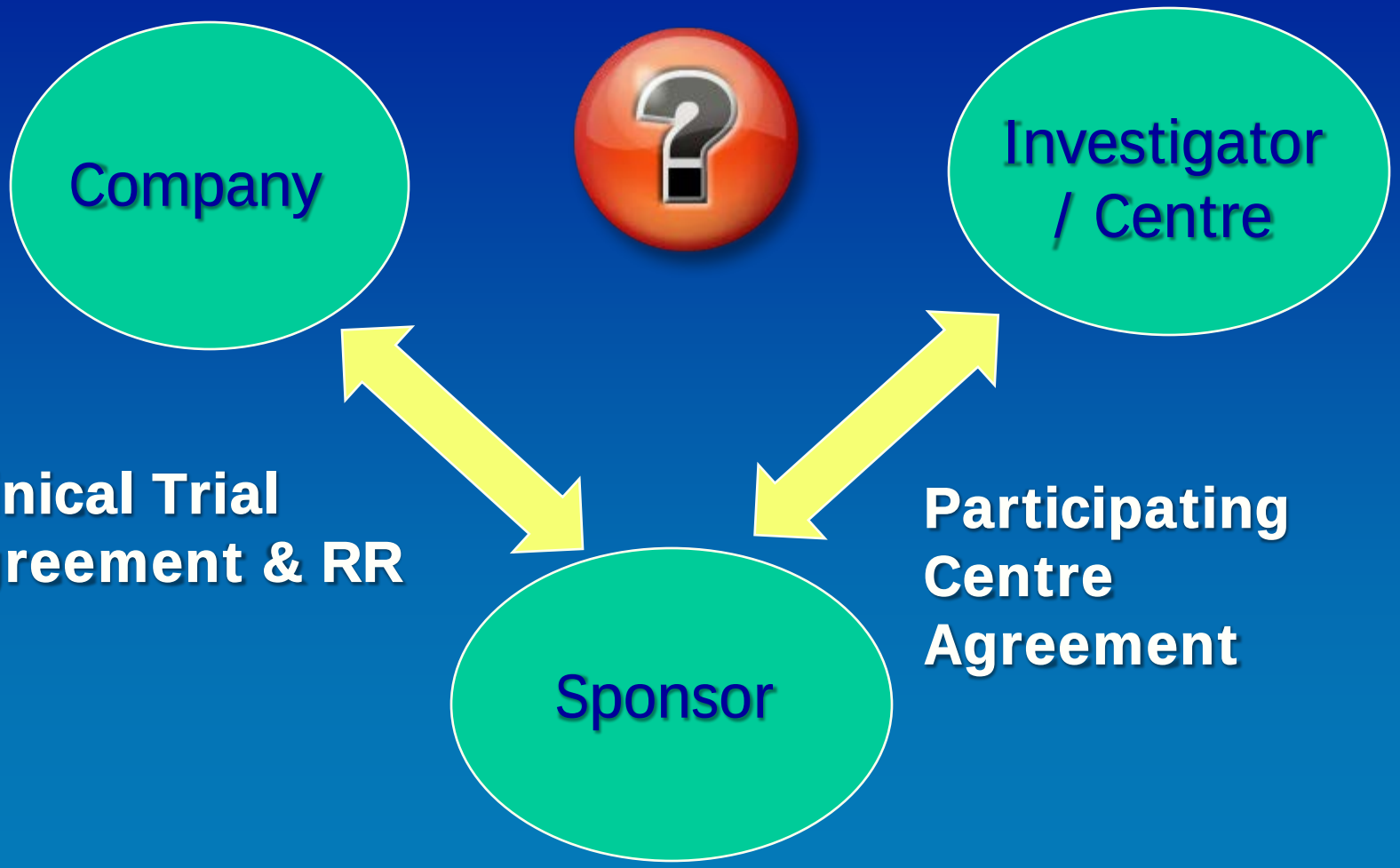
Contract Negotiations

- Indemnification (NCIC CTG sample)
  - CTG shall indemnify Company, its trustee, directors and personnel and hold it harmless from any liability, cost, or expense, including legal fees, arising out of, or in connection with, any injury to a person (including death) arising from Company's Study Drug used in this Study to the extent such injury relates directly to any negligent act by CTG and its employees pertaining to the activities to be carried out pursuant to the obligations of this Agreement.

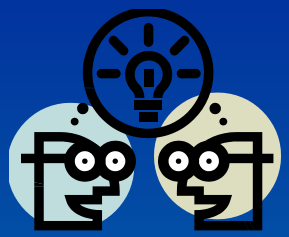
Contract Negotiations

- Similarly…Company shall indemnify and hold harmless CTG, its trustees, directors and personnel and those Participating Centres, Participating Investigators, and their respective trustees, directors and personnel (the "Indemnitee(s)") from any liability, cost, or expense, (including reasonable legal fees and expenses), including without limitation claims arising from bodily injury, including death, (individually, a "Claim") arising in connection with or arising out of: (i) the use of the Study Drug in the Study, etc….

Contract Negotiations



Contracts and Trial Timelines



#1 Bilateral Confidential Disclosure and Limited Use Agreement

#2 Clinical Trial Agreement & RR

#3 Trial Specific Participating Centre Agreement

#4 Clinical Trials Agreement; Collaborating Partner & RR

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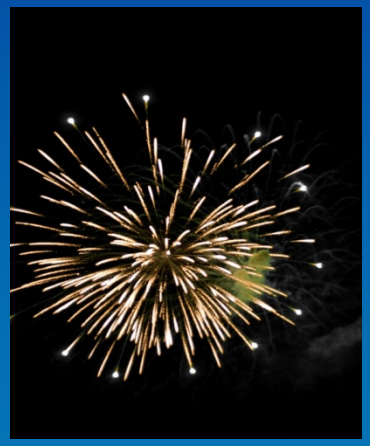
Contracts and Trial Timelines

New England Journal of Medicine



#5 Data Sharing Agreement

#6 Tumor Tissue Data Repository (TTDR)

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Investigator Perspective

- Pharmaceutical sponsored trial in which Investigator participates
  - Agreement between Investigator Institution and pharma partner
  - Details responsibilities of Investigator team in delivering the trial from an Institutional perspective
- Investigator initiated clincial trial
  - Investigator has clinical trial agreement with pharma partner to provide agent and funding
  - Investigator has submitted CTA to Health Canada
  - Investigator now responsible for delivering to pharma partner and regulatory authority from both the Investigator and Sponsor levels

Summary Contracts

- Consult with legal entity and ensure authorized signatories are aware of the research project
- Determine what type of contract and definition of roles and responsibilities will be required
- Communication with legal team during contract negotiations is important
- Contracts address more than finance and ensure expectations are clear throughout the life of a project

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