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C3PT TOOL

Likely Pharma–Academic **Pain Points and Practical Solutions**

v 1.0

MRCT CENTER
THE MULTI-REGIONAL CLINICAL TRIALS CENTER OF BRIGHAM AND WOMEN'S HOSPITAL AND HARVARD

ITCC
INNOVATIVE THERAPIES FOR CHILDREN AND ADOLESCENTS WITH CANCER

Blood Cancer United

CHILDREN'S ONCOLOGY GROUP

Purpose and Scope of Tool

This tool lays out the most problematic clauses related to data ownership, intellectual property, publication rights and trial governance in contract negotiations where the perspective of industry representatives and academic trialists may differ. The identified pain points and pragmatic solutions offered are intended as a starting point for the dialogue between parties' legal teams to facilitate contract negotiations with the aim of more rapidly agreed and executed contracts.

Introduction

Platform trials that involve collaboration between academic sponsors and pharmaceutical companies face recurring challenges around contractual agreements. Protracted negotiations around specific contractual clauses can introduce substantial and unacceptable delays to trial initiation.

We identified the most problematic clauses related to data ownership, intellectual property, publication rights and trial governance. We highlight topics that are potential 'pain points' in contract negotiations where the academic and industry perspectives can differ and offer pragmatic solutions.

These pain points and solutions should be used discussion prompts in the contract negotiation between the academic sponsor's and pharma partner's respective legal teams.

A companion document has been created with a proposed set of related model clauses that both sides may consider accepting as the default starting point for future platform collaborations. (See tool ***Intellectual Property and Data Sharing Contract Principles for Platform Trials*** »)

01 Ownership of Study Data vs Rights to Use It

PAIN POINT

ACADEMIC VIEW: "We ran the study, so the data are ours to share and reuse."

PHARMA VIEW: "We need strong, reliable rights to use all trial data globally for regulatory and commercial purposes, and we're wary of data being shared with competitors or misused."

POTENTIAL SOLUTIONS

1 Clarify "custodian vs user" roles in the contract

- Sponsor/University is **custodian/owner** of Study Data.
- Company has a **broad, clearly articulated license**:
  - Non-exclusive, worldwide, royalty-free, perpetual.
  - Explicitly allows regulatory use, HTA, partner submissions, IP filings.

2 Define onward sharing rules

- Company-specific patient-level data:
  - Cannot be given to other companies or commercial entities without the originating company's consent.
- Platform-level aggregate data:
  - Can be shared (e.g. with external academics) under agreed governance.

3 Introduce a Data Access Committee

- Joint academic-industry-patient committee to review data sharing requests.
- Transparent criteria for approval, with company given a voice (not necessarily a veto) where product-specific risk exists.

02 Product-Specific IP vs Platform/ Methodology IP

PAIN POINT

ACADEMIC VIEW: Concern that broad IP language allows the company "capture" new methods, statistical approaches, or platform infrastructure as product IP.

PHARMA VIEW: Concern that new product-related IP (e.g. biomarker signatures, new indications, responder subgroups) ends up owned by the university or even licensed to competitors.

POTENTIAL SOLUTIONS

1 Split Resulting IP into two clear categories

1. Product-Specific Resulting IP

- New indications, combinations, predictive biomarkers directly tied to the product.
- Default ownership: Company (with academic inventors named, and revenue-sharing as appropriate, under separate IP policies).
  - Non-exclusive, worldwide, royalty-free, perpetual.
  - Explicitly allows regulatory use, HTA, partner submissions, IP filings.

2. Platform/Methodology IP

- Trial design features, generic analytics, infrastructure, tools.
- Default ownership: Sponsor/Platform, with:
  - Company granted a non-exclusive licence to use these methods for its product.

POTENTIAL SOLUTIONS

2 Pre-agree a simple decision matrix

- For each IP outcome, ask:
  - Does it work only (or mainly) in this product context?→Product IP.
  - Is it generalizable across drugs or diseases?→Platform IP.

3 Offer transparent invention disclosure processes

- Joint invention review committee with clear timelines and dispute-resolution mechanisms.
- Acknowledge academic inventorship even where ownership sits with the company.

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03 Publication Timing and Control

PAIN POINT

ACADEMIC VIEW: Concern about delayed or blocked publications and perceived suppression of negative results.

PHARMA VIEW: Concern that premature or incomplete publications may:

- Reveal trade secrets.
- Undermine patentability.
- Harm regulatory strategy or investor/public perception.

POTENTIAL SOLUTIONS

1 Standardised publication timelines

- Company review: 30 days.
- Possible extension (up to 60 additional days) to file patents or address serious confidentiality/IP issues.

2 Limit the scope of company review

- Company may:
  - Remove confidential know-how (e.g. formulation details).
  - Request delay solely to file IP.
  - Correct factual errors.
- Company may not:
  - Demand deletion of robust scientific conclusions because they are unfavourable.

POTENTIAL SOLUTIONS

3 Pre-commit to a joint primary publication

- Jointly authored main results, with:
  - Clear timelines for drafting and submission.
  - A fallback mechanism if one party is slow (e.g. after an agreed period, the academic lead may proceed with appropriate acknowledgements).

4 Transparency to investigators and patients

- Include in governance documents:
  - A statement that all results (positive and negative) will be published or otherwise made publicly available within a defined timeframe.

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04 Product-Specific IP vs Platform/ Methodology IP

PAIN POINT

ACADEMICS & ADVOCATES VIEW:

Push for data sharing for secondary research and meta-analysis, including externally.

PHARMA VIEW:

Fears:

- Re-identification risks.
- Competitors using the data against them.
- Misinterpretation of early or exploratory findings.

POTENTIAL SOLUTIONS

1 Tiered data access model

- **Tier 1 – Company-specific, patient-level data**
  - Accessible to that company and the Sponsor under strict confidentiality.
  - External sharing only with:
    - Strong anonymization, or
    - Company consent.
- **Tier 2 – Pooled platform data (aggregated across drugs)**
  - Accessible to approved researchers under Data Access Committee review.
  - Sufficient aggregation to protect product confidentiality.
- **Tier 3 – Public data**
  - Highly aggregated, low-risk summaries (e.g. baseline characteristics, overall outcomes).

POTENTIAL SOLUTIONS

2 Robust data use agreements (DUAs)

- Mandatory for external requestors, covering:
  - No re-identification.
  - No attempts to infer proprietary product information.
  - Obligation to share analysis plans and results with the platform before publication.

3 Pre-specified “no-go” zones

- Agree in advance types of analyses that are too sensitive without explicit company agreement (e.g. cross-product competitive comparisons at granular levels).

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05 Monitoring, Governance, and Perceived Influence

PAIN POINT

ACADEMIC VIEW: Worry that company "rights to monitor and review" mean undue influence over the science or interpretation.

PHARMA VIEW: Needs robust oversight to ensure:

- Regulatory-grade data quality.
- Accurate safety reporting.
- Consistency with label and risk management.

POTENTIAL SOLUTIONS

1 Define separate responsibilities clearly

- Scientific governance (Steering Committee, DMC), Led by Sponsor/Platform, with independence in:
  - Endpoint definitions.
  - Analysis plans.
  - Interpretation and recommendations.
- Operational and safety oversight: company rights to:
  - Access safety data and SAEs.
  - Raise concerns about data quality or protocol deviations.

2 Joint charter for committees

- Charters describing:
  - Who votes on what.
  - When the company is an observer vs voting member.
  - Escalation paths when there is disagreement (e.g. independent arbitration, external expert review).

3 Document transparency

- Both sides receive minutes and key decision documents.
- Use neutral language in documentation to avoid the impression of one party “controlling” outcomes.

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06 Ambiguous or Inconsistent Terminology

PAIN POINT

MULTI-STAKEHOLDER VIEW:

Mixed use of terms such as Sponsor/Institution/University, Study Drug/IMP/drug name, “Data” vs “Results” vs “Study Know-How” leads to confusion and mistrust.

POTENTIAL SOLUTIONS

1 Adopt a shared glossary for platform studies

- A single definitions appendix, used in all participating company agreements, defining:
  - Sponsor, Company, Study Drug, Data, Results, Know-How, Background IP, Resulting IP, etc.

2 Map current contracts to the glossary

- Provide a short mapping for partners showing:
  - “In this agreement, ‘Data’ = [X in glossary].”

3 Use checklists when drafting

- Ensure each agreement explicitly states:
  - Who is Sponsor.
  - Who is Company.
  - Which definition set applies.

07 Future Use and "Freedom to Operate"

PAIN POINT

ACADEMIC VIEW: Want to reuse data for new, potentially unrelated questions and collaborations.

PHARMA VIEW: Wants to ensure this does not compromise freedom to operate or create IP encumbrances.

POTENTIAL SOLUTIONS

1 Pre-define categories of future use

- Low-risk: purely methodological work, pooled analyses without company-specific attribution → generally allowed with standard DAC review.
- Medium-risk: analyses that touch on a product's risk/benefit profile → require company review and possible joint collaboration.
- High-risk: analyses designed as direct commercial comparisons or to challenge regulatory decisions → require explicit company agreement or independent arbitration.

2 Offer structured collaboration slots

- For "medium-risk" ideas, propose:
  - Joint academic–industry project teams.
  - Co-authored publications.

POTENTIAL SOLUTIONS

3 Clarify that academic partners retain the right to pursue new grants and collaborations

- As long as:
  - Confidential and proprietary information is protected.
  - The agreed tiered-access and DUA frameworks are followed.
  - Which definition set applies.