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C3PT TOOL

Intellectual Property and Data Sharing Contract Principles for Platform Trials

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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 document complements the ***Likely Pharma-Academic Contractual Pain Points and Practical Solutions »*** Tool and sets out shared principles on intellectual property and data sharing for platform clinical trials conducted by academic institutions in collaboration with one or more industry partners.

Shared Objectives

All parties—academic institutions, industry partners, and patient representatives—share the following high-level objectives for the platform trial, which should be the guiding principles when negotiating the trial-related contracts:

Maximize patient and public benefit

Platform trials should generate knowledge that improves health outcomes and accelerates safe and effective therapies, while avoiding unnecessary duplication of research.

Protect participants and maintain trust

Data must be used and shared in ways that respect confidentiality, privacy, informed consent, and research ethics approvals. Transparent governance and communication are essential to sustaining public trust.

Balance academic independence and commercial realities

The framework must enable robust, independent science and timely publication, while respecting legitimate commercial and regulatory interests of industry partners.

Enable efficient, repeatable collaboration

The framework should be predictable and reusable, reducing transaction costs, shortening negotiation cycles, and supporting the long-term sustainability of platform trials.

These principles and model clauses are not intended to be legally binding but are intended to guide the drafting and negotiation of specific agreements for the platform trial.

PRINCIPLE 1 : Ownership and Custodianship

- Each party retains ownership of its **background intellectual property** (IP created prior to or outside the scope of the study).
- The industry partner ("Company") retains ownership of the **Study Drug** and all **product-related IP** and know-how.
- The academic sponsor ("Sponsor"/"University") is the **custodian of Study Data and Results** generated by the platform, and is responsible for their integrity, storage, and governance.
- **Resulting IP** arising from the conduct of the study will be treated in two categories:
    - **Product-specific IP**
      IP that relates directly and primarily to a specific study drug, its use, indications, formulations, dosing, or product-specific biomarkers will be treated as Product-Specific Resulting IP and owned by the relevant Company, with appropriate recognition of academic inventors.
    - **Platform and methodology IP**
      IP that relates primarily to the design, infrastructure, tools, or generic methodologies of the platform (e.g. adaptive designs, statistical methods, reusable analytic pipelines) will be treated as Platform/Methodology IP and owned by the Sponsor/platform, with appropriate licenses granted to participating companies as needed for their product development.

    These distinctions aim to ensure that platform trials do not appropriate company product IP and, conversely, that company agreements do not capture general platform methods as product IP.

PRINCIPLE 2 : Rights to Use and License Data and IP

- Both Company and Sponsor should have clear, broad, and appropriate rights to use Study Data, Results, and certain Resulting IP for their legitimate purposes.

- **The Company** should have rights necessary to:
    - Conduct research and development on the study drug and related compounds;
    - Support regulatory submissions and interactions worldwide;
    - Fulfil pharmacovigilance and safety obligations;
    - Conduct health technology assessments and reimbursement submissions;
    - File and defend related IP.

- **The Sponsor** should have rights necessary to:
    - Conduct non-commercial academic research, including secondary analyses and methodological work;
    - Teach and train using study data and results;
    - Support patient care where appropriate.

In practice, this will typically be achieved by:

- A non-exclusive, worldwide, royalty-free, perpetual license from Sponsor to Company to use pseudonymised Study Data, Results, and Study Know-How for defined Company purposes; and
- A non-exclusive, royalty-free license from Company to Sponsor to use Company-owned data outputs (e.g. biomarker/PK results) for defined non-commercial purposes.

All parties commit to avoiding re-identification of participants and to complying with applicable data protection laws.

PRINCIPLE 3 : Publication and Transparency

- Both Company and Sponsor should have clear, broad, and appropriate rights to use Study Data, Results, and certain Resulting IP for their legitimate purposes.
- Timely and accurate dissemination of trial results is essential for patient benefit, scientific integrity, and trust.
- Publication should not be suppressed because results are unfavorable to a product, provided that analyses are robust and methodologically sound.
- Reasonable review periods and limited delays are acceptable to protect confidentiality and patentability, but should be clearly defined and time-bound.

The parties therefore agree that:

1. A joint primary publication of the main study results is the default expectation, with both Company and Sponsor as contributors.
2. Draft manuscripts, abstracts, or presentations involving study data will be shared with the Company for review within an agreed period (e.g. 30 days), with a limited possibility of extension (e.g. up to 60 additional days) solely to enable patent filings or address material confidentiality issues.
3. Company review will be limited to:
    - Removal of proprietary or confidential information not necessary for scientific understanding;
    - Requests for delay solely for the purpose of securing patent protection;
    - Correction of factual inaccuracies.

    Company will not require removal of scientifically valid conclusions solely because they are unfavorable or neutral with respect to the study drug.

4. Following the joint primary publication, investigators should be free to publish additional analyses, subject to the same review and confidentiality framework.
5. The parties are committed to ensuring that key findings—positive, negative, or inconclusive – are made publicly available within reasonable timeframes.

PRINCIPLE 4 : Tiered Data Sharing and Governance

1. Data from platform trials should be reused responsibly to maximize scientific and patient benefit, while respecting confidentiality and protecting legitimate competitive interests.
2. A **tiered data model** will be used to distinguish:
    - **a. Company-specific patient-level data**
      Pseudonymised data at the individual patient level relating to a specific study drug. This layer is accessible to the relevant Company and Sponsor, and shared externally only under strict conditions.
    - **b. Platform aggregate data**
      Pooled or aggregated data combining multiple arms or drugs within the platform. This layer may be made available to qualified researchers under governance controls.
    - **c. Public summary data**
      Highly aggregated, low-risk summaries and results that can be shared widely, including with the public and patient communities.
3. A Data Access Committee (DAC) or equivalent governance body, with representation from academia, industry, and patient communities, will evaluate external requests to access Company-specific or platform aggregate data.
4. Data Use Agreements will require:
    - Appropriate safeguards against re-identification;

- Clear statements of permitted uses consistent with consent, ethics, and contractual obligations;
- Consideration of potential impacts on patient trust and company interests.

PRINCIPLE 5 : Governance, Monitoring, and Independence

- Scientific integrity and independence must be preserved, while ensuring robust safety and regulatory oversight.
- Scientific governance bodies such as the Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) should be led by the Sponsor/platform, with charters that:
  - Define the roles and voting rights of academic and industry representatives;
  - Preserve the independence of safety monitoring and unblinded data review;
  - Ensure transparent documentation of decisions.
- Companies should have appropriate rights to:
  - Access safety and quality data needed for regulatory compliance and pharmacovigilance;
  - Raise concerns regarding data quality, protocol deviations, or patient safety.

Clear, agreed processes should exist for resolving disagreements, including escalation to independent expert review where necessary.

PRINCIPLE 6 : Clarity and Consistency

- Consistent language builds trust and reduces misunderstandings.
- The parties will use a **shared glossary of defined terms** across agreements, including standard definitions for: Sponsor, Company, Study Drug, Study Data, Results, Study Know-How, Background IP, Resulting IP, Product-Specific Resulting IP, and Platform/Methodology IP.
- This common vocabulary should be adopted across all platform-related contracts and governance documents to the greatest extent possible.
- These principles are intended to guide the development of specific contractual terms and to support constructive, long-term collaboration between academic institutions, industry partners, and patient communities in platform trials.

ANNEX

IP and Data Sharing Model Clauses for Platform Trials

These model clauses are intended to serve as a starting point for negotiation and may be adapted as appropriate to the specific Study, the parties, and applicable local laws and regulations.

(This annex can be attached to individual collaboration or clinical trial agreements)

1. Definitions

For the purposes of this Annex:

1.1 "Background IP" means all intellectual property and know-how owned or controlled by a Party prior to the Effective Date of the Agreement or developed independently of the Study and without use of the other Party's Confidential Information.

1.2 "Study Drug" (or "Investigational Medicinal Product" or "IMP") means the investigational medicinal product(s) supplied by the Company for use in the Study.

1.3 "Study Data" means all data and information generated in the course of the Study, including pseudonymised patient-level data, case report forms, databases, and associated metadata, but excluding Results.

1.4 "Results" means aggregated or summarised Study Data and conclusions as would typically appear in a clinical study report or scientific publication, and which do not include unprocessed data or personal data.

1.5 "Study Know-How" means all non-public technical and other information, including methods, procedures, analyses, and operational know-how, generated in the course of the Study.

1.6 "Resulting IP" means all intellectual property, including patents, copyrights, database rights, design rights, trade secrets, and know-how, which arises directly from the conduct of the Study.

1.7 "Product-Specific Resulting IP" means Resulting IP that relates directly and primarily to the Study Drug, its composition, formulation, use, indications, dosing, combinations, or product-specific biomarkers or response predictors.

1.8 "Platform/Methodology IP" means Resulting IP that relates primarily to the design, conduct, infrastructure, tools, or generic methodologies of the platform (including adaptive designs, statistical methods, and analytic pipelines) and is not Product-Specific Resulting IP.

1.9 "Confidential Information" has the meaning given in the main body of the Agreement and includes Study Data and Results to the extent not publicly disclosed.

2. Ownership of Intellectual Property and Data

2.1 Background IP

2.1.1 Each Party shall retain ownership of its Background IP.

2.1.2 Nothing in the Agreement or this Annex shall operate to transfer ownership of a Party's Background IP to the other Party.

2.2 Study Drug and Product-Specific Resulting IP

2.2.1 The Company shall own all right, title, and interest in and to the Study Drug and all intellectual property and know-how relating thereto.

2.2.2 The Company shall own all Product-Specific Resulting IP. The Sponsor shall ensure that investigators and Study staff engaged by the Sponsor assign to the Sponsor, and the Sponsor shall in turn assign (or procure assignment of) to the Company all rights in the Product-Specific Resulting IP to which they are legally able to do so. The Company shall acknowledge academic inventorship in accordance with applicable laws and institutional policies.

2.3 Platform/Methodology IP

2.3.1 The Sponsor shall own all right, title, and interest in and to the Platform/Methodology IP.

2.3.2 The Sponsor hereby grants to the Company a non-exclusive, worldwide, royalty-free licence (with the right to sub-license to its Affiliates and development partners) to use the Platform/Methodology IP solely to the extent reasonably necessary for the development, regulatory approval, and commercialisation of the Study Drug and closely related compounds.

2.4 Study Data and Results

2.4.1 Subject to applicable law, patient consent, and the terms of the Agreement, the Sponsor shall own and be custodian of the Study Data and Results generated in the course of the Study.

2.4.2 For the avoidance of doubt, the Sponsor's ownership of Study Data and Results shall not confer any ownership of the Study Drug or the Company's Background IP.

3. Licenses to Use Study Data, Results and Study Know-How

3.1 License from Sponsor to Company

3.1.1 The Sponsor hereby grants to the Company a non-exclusive, worldwide, royalty-free, perpetual license (with the right to sub-license to the Company's Affiliates and development partners) to use:

(a) the Study Data (in pseudonymised or anonymised form);

(b) the Results; and

(c) the Study Know-How,

In each case solely for the following purposes:

(i) research and development relating to the Study Drug and related compounds;

(ii) obtaining, maintaining, or varying regulatory approvals;

(iii) pharmacovigilance and safety monitoring;

(iv) health technology assessments and reimbursement submissions; and

(v) filing, prosecuting, maintaining, and enforcing intellectual property relating to the Study Drug and related compounds.

3.1.2 The Company shall not attempt to re-identify any individual from the Study Data and shall comply with all applicable data protection and privacy laws.

3.2 License from Company to Sponsor

3.2.1 The Company hereby grants to the Sponsor a non-exclusive, worldwide, royalty-free license to use:

(a) Company-owned biomarker, pharmacokinetic, or similar data generated in the Study; and

(b) any Company-owned methods or tools disclosed to the Sponsor for use in the Study, solely for non-commercial academic research, teaching, and patient care, and subject to the confidentiality and data protection provisions of the Agreement.

3.2.2 Any use of such Company-derived data or tools in collaboration with commercial third parties shall require the prior written consent of the Company.

4. Data Sharing and Access

4.1 Company Access to Study Data

4.1.1 The Sponsor shall provide the Company with access to:

a) pseudonymised patient-level Study Data relating to the Study Drug (including relevant efficacy and safety variables) within [X] months of database lock;

(b) interim safety data reasonably required for pharmacovigilance, safety signal detection, and regulatory reporting; and

(c) the Clinical Study Report and/or Final Study Report when available.

4.1.2 The Parties shall agree a Data Sharing Plan specifying data formats, transfer mechanisms, and timelines.

4.2 Tiered Data Access for Third Parties

4.2.1 The Parties acknowledge that Study Data may be made available in tiers, including:

(a) Company-Specific Data: pseudonymised patient-level data specific to the Study Drug;

(b) Platform Aggregate Data: pooled, aggregated, or otherwise de-identified data across multiple Study Drugs within the platform;

(c) Public Summary Data: highly aggregated, low-risk summaries or results suitable for public dissemination.

4.2.2 Requests by third parties for access to Company-Specific Data or Platform Aggregate Data shall be reviewed and decided in accordance with the platform's Data Access Committee (DAC) or equivalent governance mechanism, as described in the Agreement or related governance documents.

4.2.3 Any third party receiving access to Study Data shall enter into a Data Use Agreement imposing obligations regarding:

(a) non-re-identification of participants;

(b) secure data handling and restricted onward transfer;

(c) adherence to the approved purposes of use; and

(d) acknowledgment of the platform and relevant Parties in publications.

5. Publications

5.1 Joint Primary Publication

5.1.1 The Parties shall collaborate in good faith to produce a joint primary scientific publication of the main Results of the Study, with authorship reflecting substantive contributions, in accordance with accepted academic standards.

5.2 Review of Publications

5.2.1 The Sponsor shall provide to the Company any proposed manuscript, abstract, or presentation that contains Study Data or Results relating to the Study Drug at least [30] days prior to the intended submission or disclosure ("Review Period").

5.2.2 Within the Review Period, the Company may:

(a) request removal of its Confidential Information that is not reasonably necessary for scientific understanding;

(b) request modifications to correct factual inaccuracies; and/or

(c) request a delay of up to an additional [60] days solely to enable the filing of patent applications covering Product-Specific Resulting IP.

5.2.3 The Company shall not require removal of scientifically valid conclusions, or otherwise block publication, solely because the Results are unfavourable or neutral to the Study Drug.

5.2.4 If the Company does not provide written comments within the Review Period, the Sponsor may proceed with submission, having taken reasonable steps to remove Company Confidential Information.

5.3 Subsequent Publications

5.3.1 Following the joint primary publication, the Sponsor and its investigators may publish additional analyses or secondary outcomes derived from the Study Data, subject to the review mechanism set out in this Section 5.

6. Governance, Monitoring, and Dispute Resolution (IP/Data/Publication)

6.1 Governance and Monitoring

6.1.1 The Sponsor shall establish and chair the Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) (or their equivalents), which shall be responsible for scientific oversight of the Study, as described in the Agreement.

6.1.2 The Company shall be entitled to representation on the TSC as [an observer / a voting member] as specified in the Agreement, but shall not participate in DMC deliberations involving unblinded data, except as permitted by applicable guidance and governance documents.

6.1.3 The Company shall have the right to monitor the conduct of the Study and to review Study Data to the extent reasonably necessary to meet its regulatory and pharmacovigilance obligations, and to ensure data quality and protocol compliance.

6.2 Dispute Resolution in Relation to IP, Data and Publications

6.2.1 In the event of any dispute between the Parties arising out of or relating to:

(a) the classification of Resulting IP as Product-Specific or Platform/ Methodology IP;

(b) the scope of any license under this Annex;

(c) access to or sharing of Study Data; or

(d) the content or timing of a proposed publication,

the Parties shall first refer the matter to a joint committee (e.g. an IP and Publications Committee) with representatives from each Party to seek resolution in good faith.

6.2.2 If the dispute is not resolved within [X] days of referral to such committee, either Party may refer the dispute to an independent expert with appropriate expertise, to be jointly appointed or, failing agreement, appointed by [a mutually agreed nominating body].

6.2.3 The Parties shall consider the expert's recommendation in good faith. If the dispute remains unresolved, it may be escalated in accordance with the general dispute resolution provisions set out in the main body of the Agreement.

7. Confidentiality and Data Protection

7.1 Confidentiality

7.1.1 Each Party shall treat the other Party's Confidential Information in accordance with the confidentiality provisions of the Agreement.

7.1.2 Study Data and Results shall be treated as Confidential Information until such time as they are lawfully and publicly disclosed (e.g. via publication or regulatory postings), subject to the data sharing and publication provisions of this Annex.

7.2 Data Protection

7.2.1 The Parties shall comply with all applicable data protection and privacy laws in connection with the conduct of the Study and the processing of Study Data.

7.2.2 Study Data provided to the Company shall be in pseudonymised or anonymised form such that the Company is not able to identify individual participants.