

Development of Alliance Agreements in the Era of Outbreaks

Key Contractual Issues in the Formation of New Alliances



Innovation & Technology Policy Lab | Global Health Innovation Alliances
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Project Summary & Objective

This project summarizes the existing sample agreements from different institutions, analyzes the key contractual issues in the formation of alliances, and develops master charts of legal provisions to compare different approaches, to provide a reference for the formation of new alliances in the era of epidemic disease outbreaks.

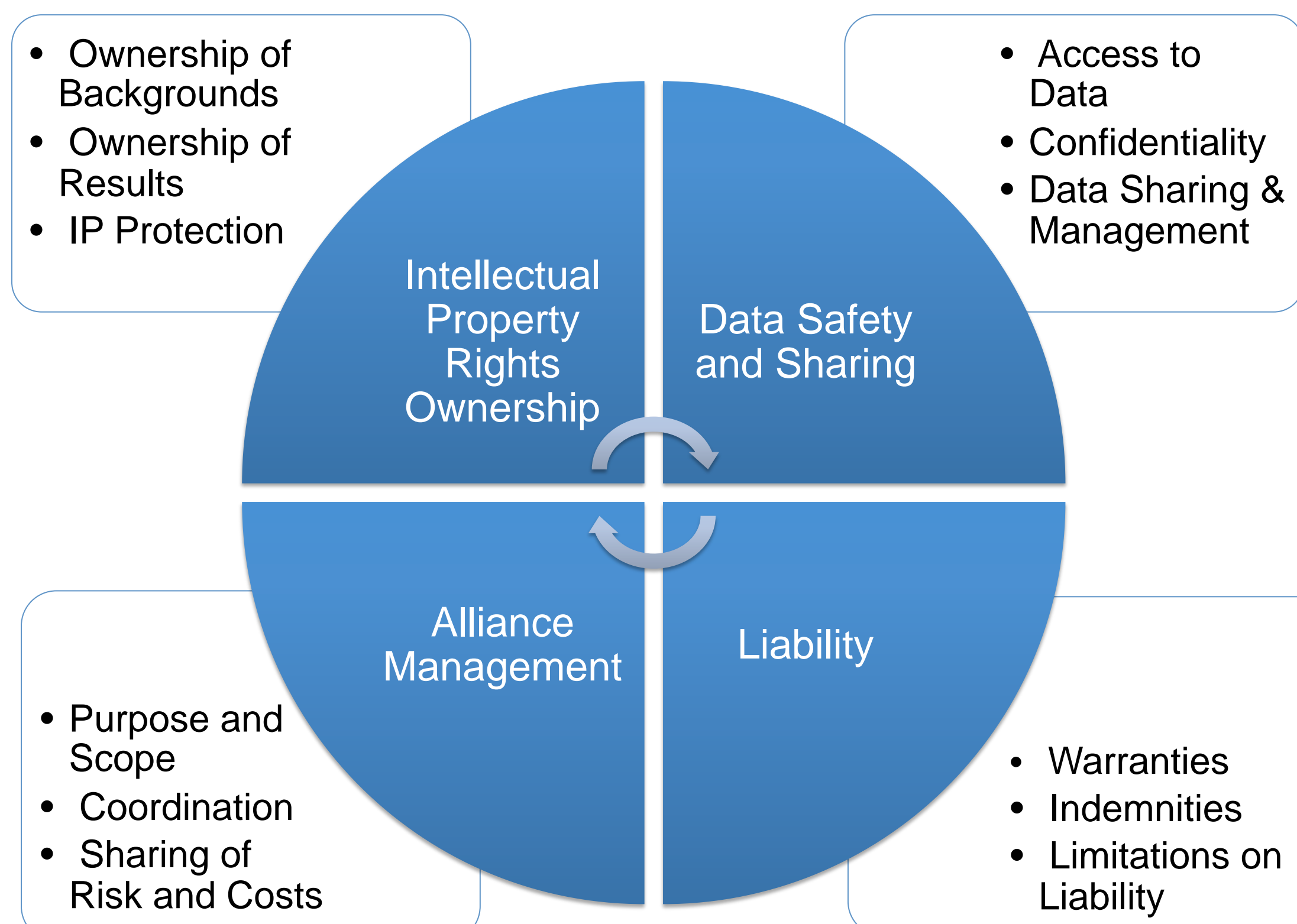
Methodology

- Reviewed existing model and related agreements;
- Identified applicable key terms;
- Identified major approaches to specific issues;
- Developed master chart of specific terms from designated agreements;
- Adapted existing terms to the needs of a multi-party alliance for development of vaccines and therapies to treat and protect against an epidemic disease outbreak.

Categories of Agreements

- Consortium/Inter-institutional Agreements
- License Agreements
- Material Transfer Agreements
- Data Sharing Agreements
- Non-Disclosure Agreements

Key Issues



IP Ownership

Issue	Model Approaches
Ownership to Existing IP/Backgrounds	Existing IP remains the exclusive property of their owners. The owner of the background technology remains free to license or transfer their ownership rights. The recipient of the background technology does not obtain any right in any of the materials or data furnished from the supplier, and agrees not to seek any IP rights in the backgrounds.
Use of Backgrounds Technology	License: (i) royalty-free; (ii) non-exclusive; (iii) non-sublicensable; (iv) nontransferable. Purpose: The backgrounds must be used for the purpose to carry out this project. Further license is needed for any purpose beyond this project. Licensed Field of Use & Licensed Territories: The licensed patents can only be used in Licensed Field of Use and Licensed Territories (both to be defined). Royalty: The access rights to the background are royalty free.
Ownership of Results	Ownership: The party that creates or generates the result own the IP in that result. Joint Ownership: If the results are created or generated by two or more parties jointly. Assigned to Entity: The owner will make sure the IP is properly assigned to the entity by the employee or student inventor/creator. Report of Improvement: The licensee has a reporting obligation to the Licensor on any improvements/results. Grant Back: Licensee grants to Licensor a (i) nonexclusive, (ii) royalty-free, (iii) worldwide, (iv) sublicensable license to all improvements, methods, modifications and other know-how developed by or on behalf of Licensee. Right of First Refusal: Licensor will have a ROFR on improvements. Transfer of Improvement: Upon request of the Licensor, the Licensee shall transfer to the Licensor any know-how owned or controlled by Licensee relating to such improvement.
Protection of Results	Protection by Owner: Owner of the Result will have the sole discretion in register or maintain protection or sue for infringement. Protection by Lead Entity: The Lead Entity has the responsibility, authority and ultimate discretion to seek patent protection. It must keep other entities reasonably informed. Middle Approach: The beneficiary who owns the results must adequately protect them. If it fails to do so, the joint undertaking may assume the ownership of the results to protect them.
Access to Results	Access Rights: The access rights do not include a right to sublicense, and must be exercised through a request in writing. Access Rights to Implement: Each party has access rights to results to the extent necessary to implement this joint undertaking. Such access rights are royalty free. Access Rights to Exploit Results: Parties will have the access rights to the results only to the extent reasonably required for the purpose of the research use of results.
Exploitation of Results	Exploitation by Owner: The beneficiary who owns the result has the right to exploit the result. Exploitation by Lead Entity: The Lead Entity has the exclusive authority and final discretion to negotiate, execute, and administer license agreements. Exploitation by Other Members: There is a royalty-free, non-exclusive license to use the result for other members of the project for the purpose of this project.

Data Safety & Management

Issue	Model Approaches
Access to Data	Limited Purpose: Stability data and other know-how are used only for the purpose of this agreement. Limited Recipients: The Recipient shall only authorize access to the Confidential Information to its Representatives whose knowledge is necessary to enable the Recipient to carry out the Project.
Confidentiality	Confidentiality Obligation: Reasonable efforts to keep the confidentiality of such information. Return or Destruction upon request. Exceptions: (i) other source of information; (ii) disclosure pursuant to law and regulation; (iii) release approved by the owner; (iv) for academic publication without notice; (v) disclosure to funding body under funding conditions.
Data Management	Establishment of good data management practices. Pooling of data for easy sharing and use. Open access to research data for public use.

Liability

Issue	Model Approaches
Warranties	Warranties of Non-Infringement. None of the parties makes any warranty or representation.
Indemnity	Mutual Indemnification: The parties indemnify each other against any claims made as a result of the indemnifying party's use of Result or other materials from the indemnified party. Recipient Indemnity: Recipient of materials or data shall indemnify the Suppliers. Exceptions: No indemnification for the indemnified party's negligence, deliberate breach of this agreement, and its intentional infringement to third party's IP.
Limitations of Liability/Damages	Self-responsibility: Each party is responsible for its own part of the collaborative activities. Indirect Damages: No Liability for Indirect Damages. Cap: The parties can set a cap for the aggregate damages.

Conclusion

- The legal framework substantially affects the outcome and efficiency of the alliance formation.
- The four key issues are usually central of the negotiation.
- Which approaches to adopt is determined by the purpose and scope of the alliance.

Reference List

Institutions	Names of Agreements
AUTM	1. AUTM Model Inter-Institutional Agreement (Annotated)
Boston University	1. Boston University Startup Exclusive License
British Government (Lambert Toolkit)	1. Lambert Toolkit Model Consortium Agreement D
Gates Foundation	1. CAVD Data & Materials Sharing Agreement
Innovative Medicines Initiative (IMI)	1. IMI Model Grant Agreement
Medicines Patent Pool (MPP)	1. License Agreement between the MPP and Gilead 2. License Agreement between MPP and MSD (Merck) for Paediatric Formulations of Raltegravir 3. License Agreement between MPP and University of Liverpool 4. License Agreement between MPP and AbbVie regarding LPV/r
National Institutes of Health (NIH)	1. Exclusive Patent License Agreement 2. Non-exclusive Patent License Agreement 3. Non-exclusive Patent License (Sublicensable) Agreement 4. Biological Materials License Agreement 5. Commercial Evaluation License Agreement
World Health Organization (WHO)	1. Standard Framework Memorandum of Understanding 2. Project Collaboration Agreement 3. Template Collaboration Agreement with WHO 4. Template Material Transfer Agreement 5. Mutual Confidentiality Disclosure Agreement 6. Ebola Country Request Letter

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