BUILDING ACCESS INTO PHARMACEUTICAL R&D AGREEMENTS: IDEAS AND POSSIBILITIES FROM REAL-WORLD CONTRACTS

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The Role of Contracts in Addressing Key Global Health Issues

The interconnectivity (or not) of policies and contracts

- Policymakers and organizations anticipate that their policies will be implemented—but they don't always think about how they'll be implemented.
- Those drafting agreements try to interpret policies through the provisions they draft and negotiate, but leverage and practicalities impact the final contract.
- The confidentiality obligations imposed on the majority of agreements keep both groups from viewing the range of options and the actual language used to impose the enforceable obligations in a wide range of agreements.
- The terms used in policies and by academics often are different—or differently defined—than terms used by lawyers and business people.
- Without understanding BOTH the goals of policies AND the realities of contract negotiations, it is difficult to achieve the intentions of the policy goals.
- A contract must result in mutually agreed obligations that make contractunderstandable, enforceable, and trackable.

The interconnectivity of different types of agreements

- Confidentiality agreement
- Material transfer agreements
- Development agreements
- License agreements
- Manufacturing and supply agreements
- Technology Transfer agreements

Key issues addressed by contracts for funding joint development agreements

- Intellectual property ownership
  - Background
  - Foreground
- Access – tech transfer, step-in and Trusted Partners
- Liability and indemnification
- Sustainability
- Territory and vaccine nationalism
- During and Post-pandemic changes

All terms are interrelated in an agreement (and negotiated as a whole)

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What is (and the goal of) the MAPGuide?*

*Many thanks to the Wellcome Trust for recognizing and supporting our efforts!

What is the MAPGuide?

- An annotated index of actual and template contractual provisions from global health alliance agreements.
- Real-world examples from public sector, industry, nonprofit, philanthropic, and multilateral institutions.
- A user-friendly tool that allows practitioners and policy-makers to navigate content easily.
- A robust and flexible online platform that will support expansion of both content and functionality
- A way of looking across agreement provisions by stage of development, type of product, type of organization and type of agreement
- A potential research tool

What isn't the MAPGuide?

- A template for creating global health alliance contracts
- An assessment of the quality of any of the agreements contained within the agreements
- A full educational tool that explains why some provisions are better for different stages of development and different types of products (although they certainly are and we hope it does illustrate this point)
- Complete! We need many more agreements and provisions in order to better illustrate the range of issues and the range of provisions which address those issues.
- Static or fixed in time. It is regularly updated.

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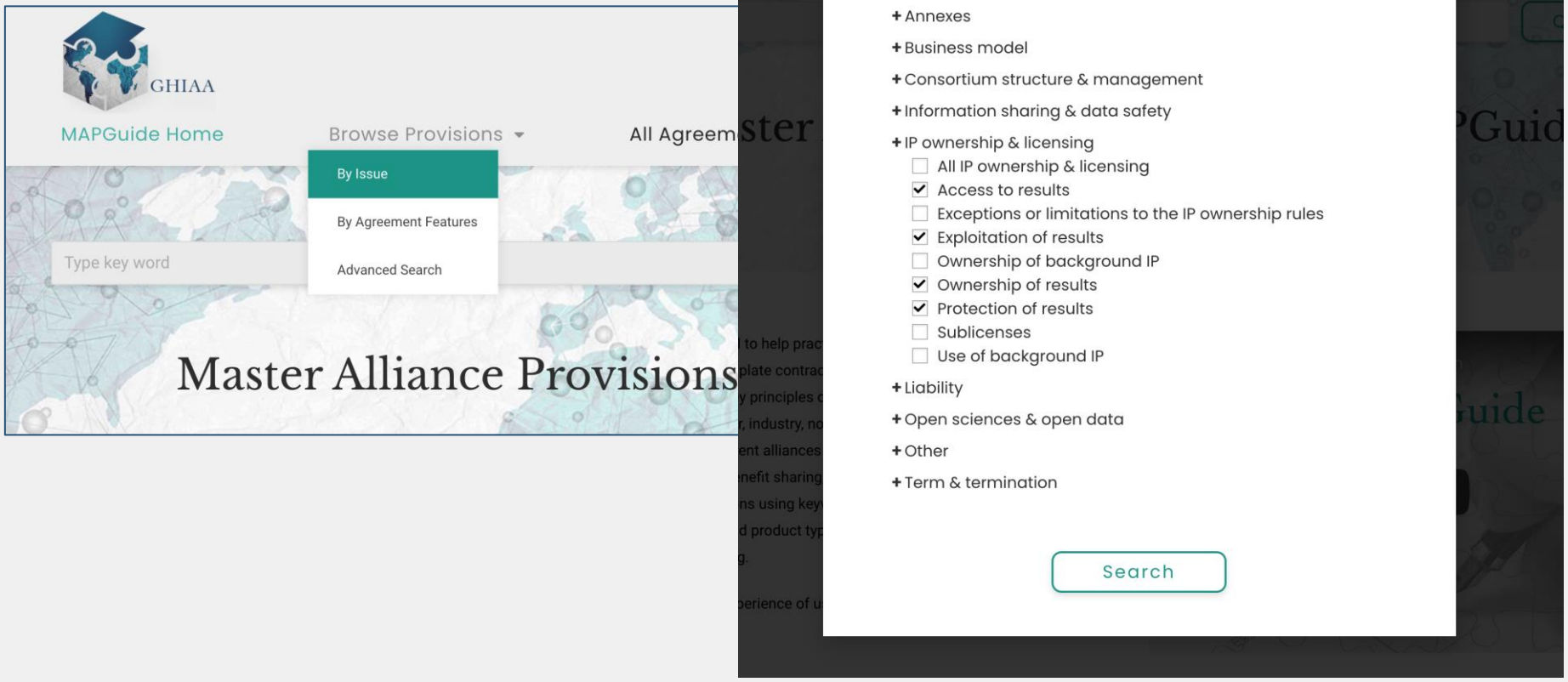
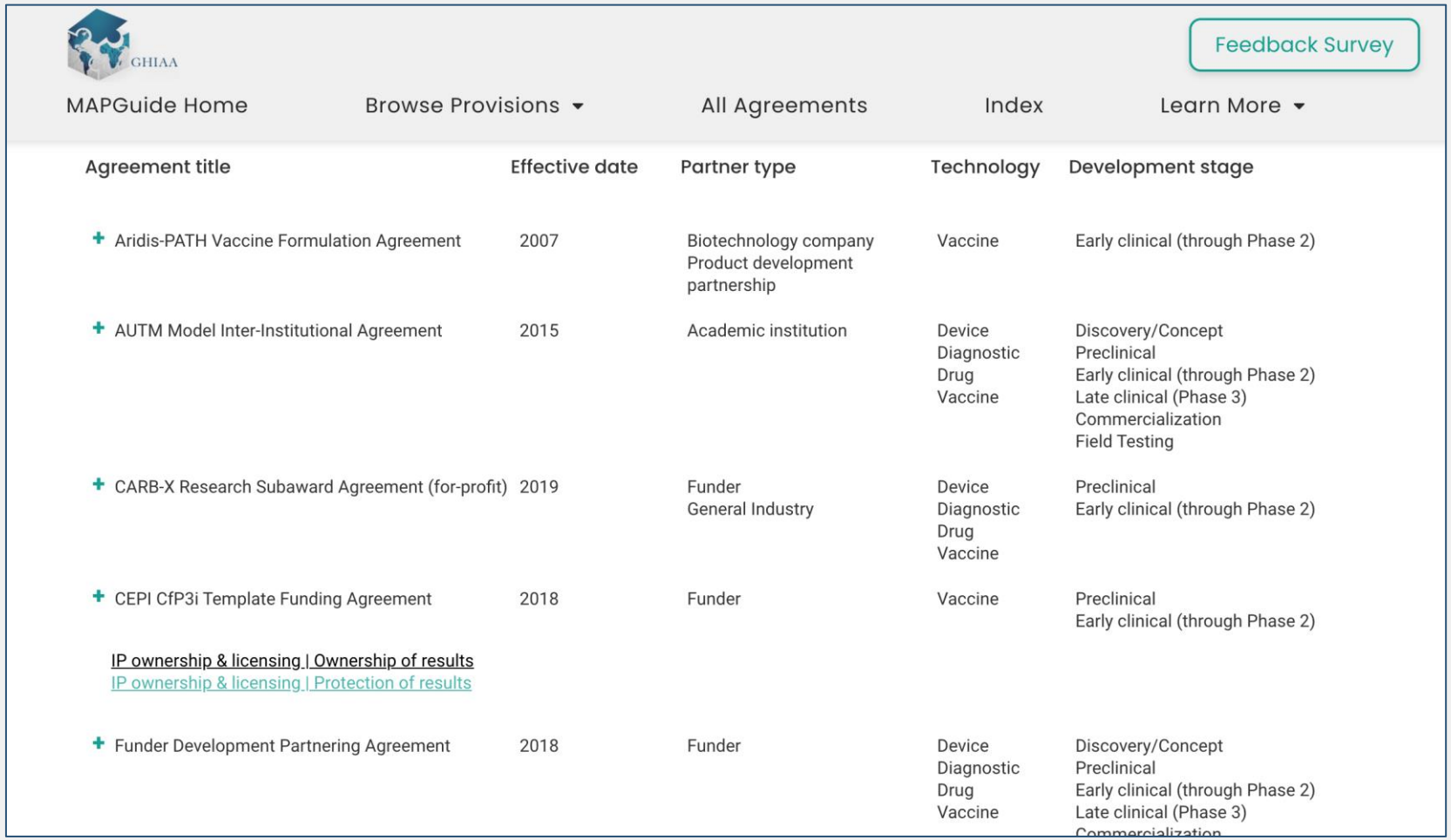
Example Issue Search: Intellectual Property

Example issue: Search



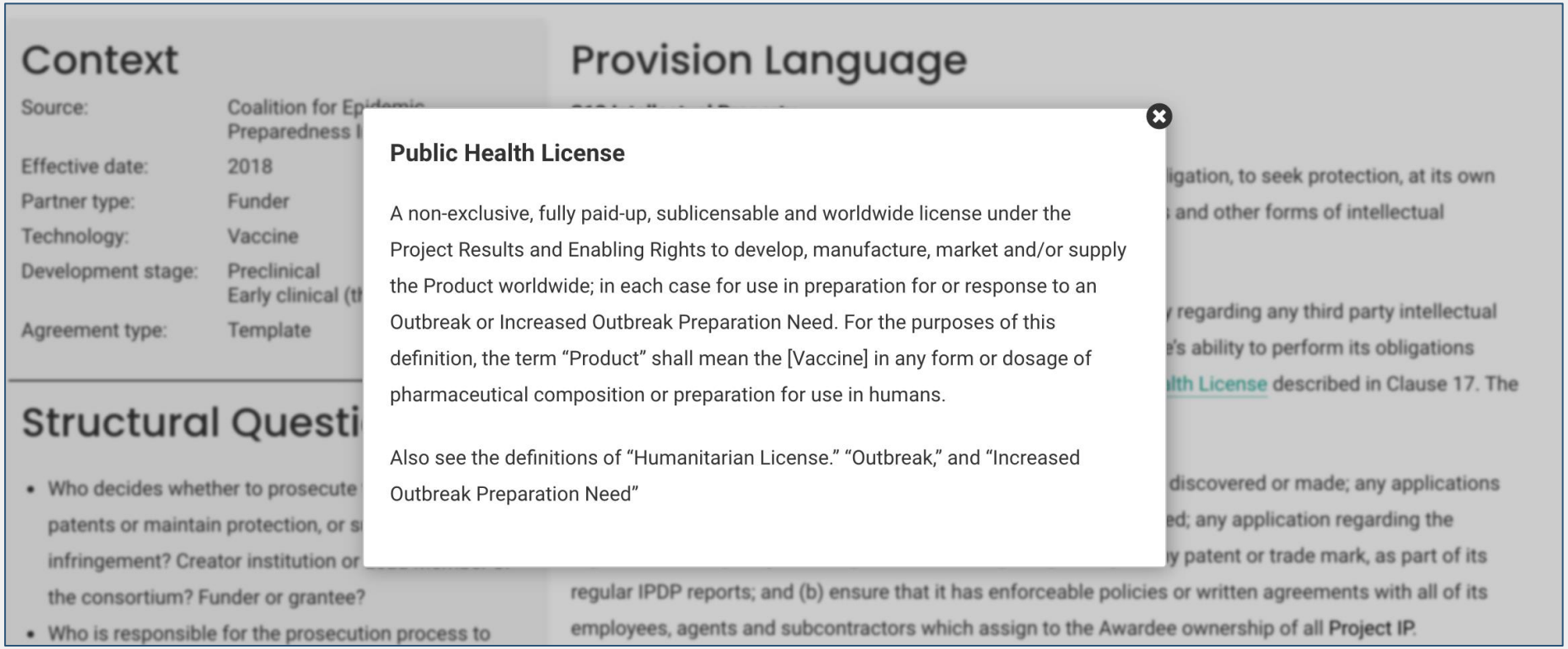
Example issue: Results



Agreement title	Effective date	Partner type	Technology	Development stage
+ Aridis-PATH Vaccine Formulation Agreement	2007	Biotechnology company Product development partnership	Vaccine	Early clinical (through Phase 2)
+ AUTM Model Inter-Institutional Agreement	2015	Academic institution	Device Diagnostic Drug Vaccine	Discovery/Concept Preclinical Early clinical (through Phase 2) Late clinical (Phase 3) Commercialization Field Testing
+ CARB-X Research Subaward Agreement (for-profit)	2019	Funder General Industry	Device Diagnostic Drug Vaccine	Preclinical Early clinical (through Phase 2)
+ CEPI CfP3i Template Funding Agreement	2018	Funder	Vaccine	Preclinical Early clinical (through Phase 2)
IP ownership & licensing | Ownership of results IP ownership & licensing | Protection of results				
+ Funder Development Partnering Agreement	2018	Funder	Device Diagnostic Drug Vaccine	Discovery/Concept Preclinical Early clinical (through Phase 2) Late clinical (Phase 3) Commercialization

Example issue: Provision

Example issue: Definitions



Discussion points

- How might the MAPGuide be a useful tool in analyzing COVID-19 related agreements?
- What issues should we look to address through new agreement provisions?
- What are the best sources for additional agreements?
- How can we use the MAPGuide to encourage discussion of the language and provisions across stakeholders and to compare policies to the resulting agreement language
- The two glossaries
- Next steps and sustainability

Needed: Feedback from you!

Please review the MAPGuide
and fill out our user survey.
We want to make it responsive to
your needs.

Thank you!

Questions?

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