The background of the slide is a dark blue field filled with a pattern of interlocking puzzle pieces. In the upper right corner, a portion of a world map is visible, showing the continents of North and South America in a lighter blue and green color, set against a white background.

Jaharis Symposium: Health Law and Intellectual Property

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April 29, 2021



GHIAA

Equitable Access To Vaccines: the role of Step-in Rights and Technology Transfer

The Development, Production and Distribution of
COVID-19 Vaccines and Medicines

What's Different About Contracts for Public Health Products?



- Intense scrutiny/transparency requests
- Balancing of public/private interests
- Commercial plus public health markets?
- Expectations – how much profit seems fair?
- Pricing terms
- Liability and indemnification coverage
- The main funders/buyers – Foundations, government, procurement agencies
 - Unique funders' requirements (e.g. equitable, affordable and sustainable access)

Key Issues Addressed by Joint Development Funding Agreements



- **Equitable Access** – tech transfer, step-in and Trusted Partners
- **Intellectual property ownership (Background/Foreground)**
- Liability and indemnification
- Sustainability
- Territory and vaccine nationalism
- During and post-pandemic changes
- Termination / enforcement

The background of the image features a light gray grid of interlocking puzzle pieces. Four of these pieces are solid blue, located at the top-left, top-right, bottom-right, and bottom-center positions. The remaining pieces are white and contain faint, high-resolution images of various white pills and capsules, including round tablets and oblong capsules, some with visible markings.

Equitable Access

The Concept of Equitable Access: Example from a Vaccine Funder



- The **Coalition for Epidemic Preparedness Innovations** (CEPI) is committed to achieving equitable access to the outputs of **all** CEPI-supported programs including vaccines, platforms, data, results, and materials.
- Equitable access to epidemic vaccines in the context of an outbreak means that appropriate vaccines are first available to populations **when and where they are needed** to end an outbreak or curtail an epidemic, regardless of ability to pay.
- It also means that CEPI will ensure **open access** to data, results and publications arising from its funding and facilitate access to materials to accelerate vaccine development.

The Concept of Equitable Access: Example from a Company



Eli Lilly and Company's monoclonal antibody combination therapy

1. **Allocation:** Treatment will be allocated based on unmet medical needs globally.
2. Patient **Cost:** The goal is for patients to have no out-of-pocket costs for such antibody treatments, wherever possible.
3. **Pricing** to Health Systems: Equitable government pricing will be tiered based on a country's ability to pay.



Key Components of Access

- **Sustainability Mechanisms – tech transfer, step-in and Trusted Partners**
 - **Intellectual property ownership and control**
- Transparency and data sharing
- Cost transparency and price
- Liability and indemnification

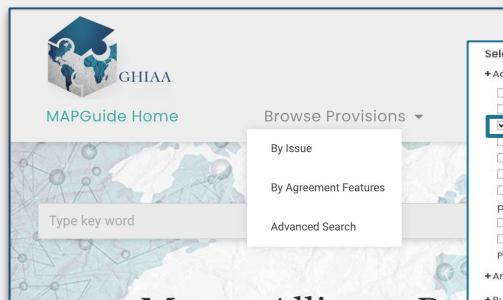
All should interact and seek to ensure that the funder's investment results in an affordable, available medical product for populations in need.



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Step-in Rights and Technology Transfer

GHIAA MAPGuide: Step-in Rights and Technology Transfer



Select Issue or Sub-Issues

- + Access to medicines
 - ☐ All Access to medicines
 - ☐ Equitable access
 - ☒ Funder step-in rights
 - ☐ Outbreak preparedness
 - ☐ Pandemic Products
 - ☐ Policy considerations
 - ☐ Affordable or reasonable pricing
 - ☐ Public health licenses
 - ☐ Supply/Purchase of Products
- + Annexes
- + Business model
- + Consortium structure & management
- + Information sharing & data safety
 - ☐ All information sharing & data safety
 - ☐ Confidentiality
 - ☐ Data management
 - ☐ Exceptions and limitation the confidentiality obligation
 - ☐ Information sharing
 - ☐ Material transfer
 - ☒ Technology transfer
- + IP ownership & licensing
- + Liability
- + Open sciences & open data
- + Other
- + Term & termination

Search Results For:

- Issue:
- Access to medicines | Funder step-in rights
 - Information sharing & data safety | Technology transfer

(Click + to show provisions)

Agreement title	Effective date	Partner type	Technology	Development stage
+ Collaboration and License Agreement between Sanofi and Translate Bio, as Amended	2020	Biotechnology company Multinational pharmaceutical company	Vaccine	Discovery/Concept Preclinical Early clinical (through Phase 2) Late clinical (Phase 3)
+ Funder Development Partnering Agreement	2018	Funder	Device Diagnostic Drug Vaccine	Discovery/Concept Preclinical Early clinical (through Phase 2) Late clinical (Phase 3) Commercialization Field Testing
+ Merck-BSC License Collaboration Agreement	2014	Biotechnology company Multinational pharmaceutical company	Vaccine	Early clinical (through Phase 2) Late clinical (Phase 3) Commercialization
+ MPP-BMS Sublicense & Tech Transfer Agreement	2017	Multinational pharmaceutical company Other nonprofit	Drug	Commercialization
+ MPP-Gilead License Agreement	2011	Multinational pharmaceutical company Other nonprofit	Drug	Commercialization
+ WHO Template Material Transfer Agreement	2015	Multilateral organization	Device Diagnostic Drug Vaccine	Discovery/Concept Preclinical Early clinical (through Phase 2) Late clinical (Phase 3) Commercialization Field Testing

[See full search results in the MAPGuide®](#)

Step-in Rights: Development Agreement Example



U.S. Government/company agreement

"In the event (a) Sanofi elects to terminate the manufacturing or discontinue the sale of the vaccine, and (b) Sanofi has submitted an Emergency Use Authorization or a BLA application, then upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product vaccine with a third party for exclusive sale to the U.S. Government:

- a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Sanofi Background Patent, Copyright, other Sanofi Intellectual Property, Sanofi Know-How, Sanofi Technical Data rights necessary to manufacture or have manufactured the vaccine;
- b. necessary FDA regulatory filings or authorizations owned or controlled by Sanofi related to this product vaccine and any confirmatory instrument pertaining thereto (excluding with respect to [redacted content]); and
- c. any outstanding Deliverables contemplated or materials purchased under this Project Agreement."

Also:

The Government has the right to exercise a Most Favored Nation Clause, licensing rights and march-in rights under the Bayh-Dole Act, and reasonable scope of data rights

[See the MAPGuide for more detail](#)

Step-in Rights: Purchasing Agreement Example



European Union/company agreement

“In addition, the contractor will transfer, upon the Commission's request to be provided within forty- five (45) days after the receipt of notification about the automatic termination, to the Commission, or a third party named by the Commission, any raw materials and primary components not used and paid for with the up-front payments (the “Refundable Items”). The contractor will also facilitate the discussion of a transfer of reserved capacity with CMOs [Contract Manufacturing Organization] paid for with the up-front payments to a third party selected by the Commission.”

[See the MAPGuide for more detail](#)

Technology Transfers - A Limited Remedy



How well do technology transfers actually work and what are the barriers to success?

Success Factors:

- Willing transferor
- Capabilities of recipient
- Complexity of the process
- Underlying IP availability
- Availability of necessary materials and components



Thank you!

Questions?

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Appendix 1: GHIAA Resources

GHIAA Resources



- The [GHIAA MAPGuide®](#) - search for global health agreement provisions by partner type, development stage, technology type and/or key issue.
- The [Glossary of Global Health Agreement Terms](#) - a new resource containing different interpretations of commonly used terms in global health agreements.
- MAPGuide [Resources & Analysis page](#) - we will be adding new blog posts and articles to this page over the coming months. We have just published the first section which provides a summary of funder approaches to the question of equitable access.

Why we developed the MAPGuide?



- **Before** COVID-19...the **2014 Ebola outbreak** in West Africa exposed significant gaps in pandemic preparedness.
- Despite rapid scientific progress, the formation of R&D collaborations to develop vaccines/therapeutics was hindered by a **lack of legal clarity** regarding alliance structures, technology transfer, and data sharing.
- GHIAA began to research the partnerships formed between the public, private, and non-profit sector, and the challenges that they faced. We identified the need for a tool to help stakeholders to consider **key issues for global health agreements**, and see how they could be addressed.



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Appendix 2: Example provision

Step-in and U.S. COVID-19 Agreements

(different language used in different agreements)



Example provision: Novavax

In recognition of the Government's significant funding for the development and manufacturing of the product in this Project Agreement and the Government's need to provide sufficient quantities of a safe and effective COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security...

Novavax, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of the NVX-CoV-2373 vaccine with a third party for exclusive sale to the U.S. Government [...]