



# Socially Responsible Licensing Practices

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# About GHIAA & the MAPGuide



GHIAA provides tools and resources for developing policies and agreement provisions that will **facilitate equitable access to medical innovations**.

Our **MAPGuide<sup>®</sup> Platform** provides open access resources including:

<b>Provision Database</b>	Analysis of provisions from funding, licensing, technology transfer, and procurement agreements.
<b>Equitable Access Glossary</b>	Explanations of terminology used for the development, negotiation & implementation of equitable access policies and provisions.
<b>Equitable Access Policies</b>	Examples of policies from funders, PDPs and academia.



# Key Terminology



## Equitable Access

Appropriate medical products are sustainably available and affordable to all populations in need, when they are needed.

### Core components

- **Affordable** - product priced so that it can be purchased by all who need it
- **Available** - product registration & distribution
- **Appropriate** - suitable product characteristics
- **Sustainable** - product accessible on an ongoing basis at prices & volumes that are viable for product manufacturers

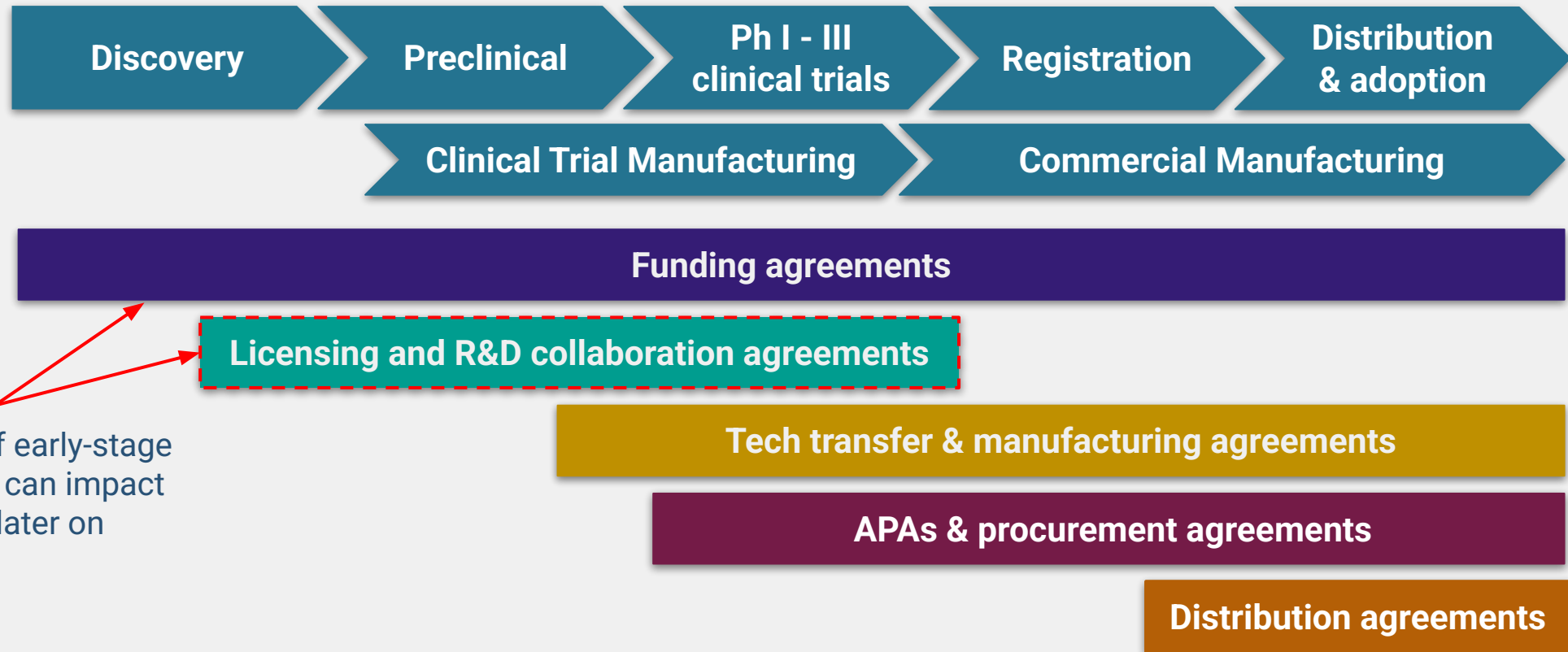
## Socially Responsible Licensing

Licensing of intellectual property by an innovator (e.g. university) in a manner that facilitates equitable access.

### Potential approaches

- **Non-exclusivity** - allowing multiple licensees to compete and/or address different markets
- **Reserved rights** - research use, humanitarian use or unmet needs
- **Access conditions** - specific obligations to facilitate access to licensed product
- **Licensee selection** - MPP, product development partnerships, LMIC developers

# The Role of License Agreements in the R&D Process



Provisions of early-stage agreements can impact access later on

# Example Access Conditions (2/2)



- **Access plans**

- Requirement to **develop a plan** for access and affordability in certain markets.
- Provisions in the plan can be **tied to certain development milestones**.
- Can include use of **sublicensing & partnerships**.

- **Non-filing/non-enforcement of patent rights**

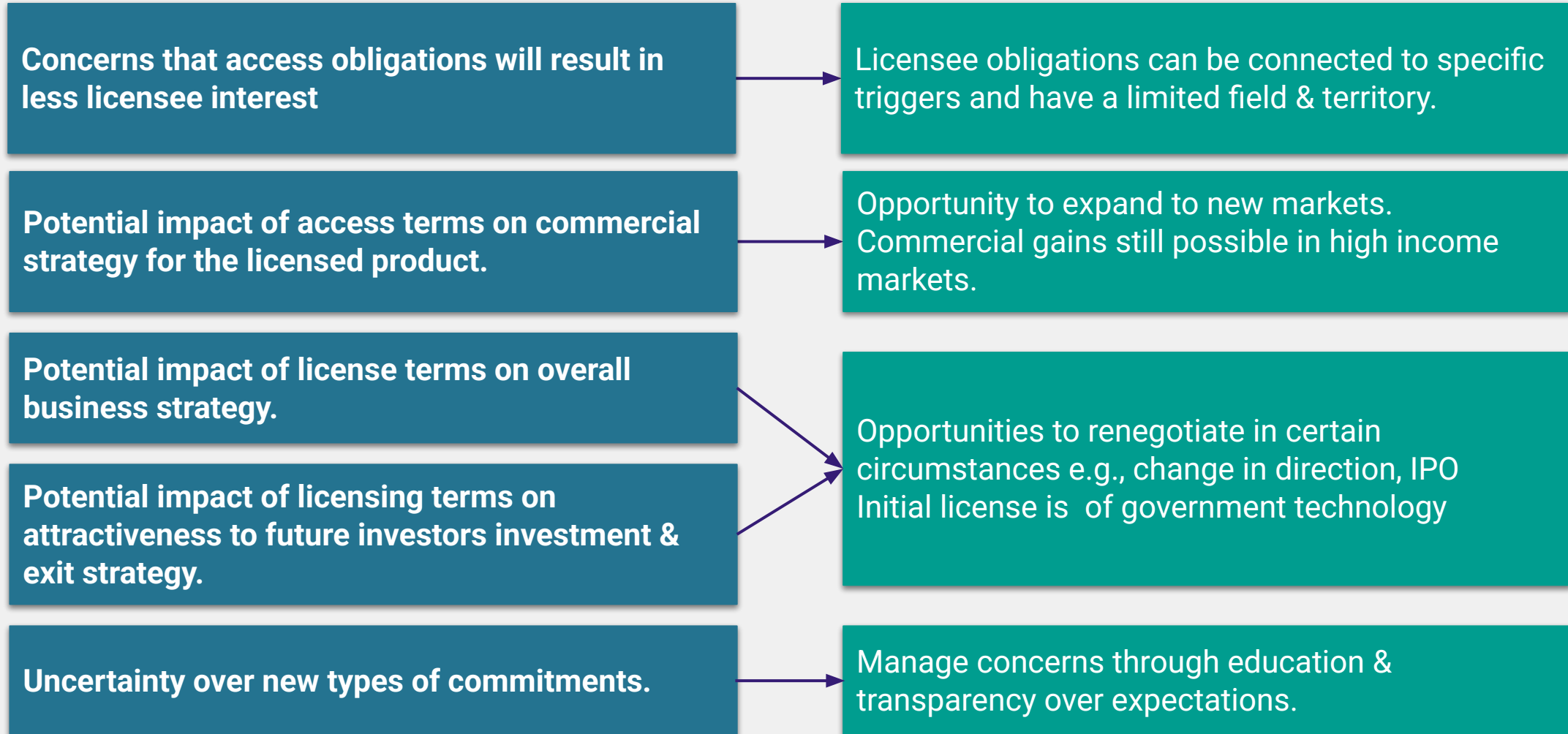
- Licensor **retains decision-making rights** for LMIC filing on a case-by-case basis.
- **No patent enforcement** to prevent sale of products in LMICs, but may be permitted to prevent manufacturing in LMIC for sale to HIC.

# Example Access Conditions (1/2)



- **Affordability & availability commitments**
  - Often a **best/reasonable efforts** commitment or stated objective of achieving affordable pricing in certain markets.
  - **Diligence obligation or first right** to commercialize in certain markets.
  - **Royalty discounts**
- **Humanitarian use/unmet need reservations**
  - Allows the innovator to **grant further licenses** to meet the needs of underserved populations if the licensee cannot or will not do so.
  - Often phrased as '**humanitarian use.**'

# Common Negotiating Challenges & Responses





# Example Approaches to Access in Licensing Agreements

# Access Plans



## UC Berkeley Exclusive License Template Agreement

*Within three (3) months of receiving FDA (or its foreign equivalent's) approval of a Licensed Product, Licensee will provide the Regents with either (a) an Affordable Access Plan (defined below), or (b) a written explanation as to why such an Affordable Access Plan is not needed or infeasible. [...]*

*The "Affordable Access Plan" means Licensee's and/or its Sublicensees' **plans (including strategies and timelines)** reasonably intended to **support affordable access** in a) **Low and Middle Income Countries** as defined by the World Bank Group ("LMICs"), and b) **vulnerable, underserved, and special needs populations in the U.S.**, as defined by the Department of Health and Human Services, **such as through licensing or partnerships** including with non-profit organizations. [Click for full text.](#)*

# Non-Filing / Non-Enforce



## Harvard – Tectonic Therapeutic, License Agreement

Harvard **expressly reserves the right to decline** Licensee's request to file, prosecute, maintain or defend any of the Patent Rights in any Developing Country(ies) **unless** Licensee demonstrates to Harvard's reasonable satisfaction that the filing, prosecution, maintenance or defense of such Patent Rights in such Developing Country(ies) would **materially increase the locally-affordable availability** of Licensed Products or equivalents thereof (e.g., generic products) in those and/or other Developing Country(ies).

[Click for full text.](#)

## Yale University - BIND Biosciences, Cancer Therapeutic, Exclusive License Agreement

**Neither Licensee nor Yale shall take any action to enforce the Licensed Patents, in low or lower-middle income countries**, where such action is intended to prevent the sale of Licensed Products in any such countries. However, Licensee and/or Yale may take such action in any such country, provided that such action is intended to prevent the manufacturing, use or sale of Licensed Products for export to countries that are not low-income or lower-middle countries. [Click for full text.](#)

# Affordability & Availability



## **UCLA – Radiopharm Theranostics, Cancer Therapeutic & Diagnostic (DUNP19 antibody) License Agreement**

*WHEREAS, as part of its public mission to bring products to the marketplace, The Regents uses **good faith efforts to enable underserved communities**, which have limited access to adequate quantities of medical innovations arising from UCLA’s laboratories, to have **affordable access** to these innovative products.*

[Click for full text.](#)

## **Harvard – Tectonic Therapeutic, License Agreement**

*Licensee, together with its Subsidiaries and/or Sublicensees, shall have the **first right to develop, manufacture, have manufactured, import, have imported, offer for sale, sell, have sold or otherwise distribute or have distributed** such Licensed Product or equivalent thereof (e.g., a generic product) to make such Licensed Products **generally available at locally-affordable prices in any Developing Country(ies) which are chosen by Licensee** and/or its Subsidiaries and Sublicensees in their sole discretion. Sales of such Licensed Products in Developing Country(ies) generally available at locally-affordable prices shall be entitled to the **royalty discounts** set forth in Section [X] of the Agreement. [Click for full text.](#)*

# Humanitarian Licenses



## UC Berkeley, Therapeutics & Diagnostics, Exclusive License Agreement Template

*“Humanitarian Purposes” means: (a) the use of Licensed Products and Licensed Services for **research and development** purposes by any nonprofit organization or other third party, anywhere in the world that has the express purpose of developing the Licensed Products or Licensed Services **for use solely for protection from, treatment of, or diagnosis of Neglected Diseases in a Low- or Middle-income country** as that term is defined by the World Bank (hereinafter “LMI Country(ies)”); (b) **Sale** of Licensed Products and Licensed Services in LMI Countries **at or below the cost** of manufacture and distribution.*

*Regents further **reserves the right to license** Regents’ Patent Rights to any third parties solely for Humanitarian Purposes. Such licenses for Humanitarian Purposes will (i) **expressly exclude** the right of the third party licensee to export or Sell the Licensed Products from a LMI Country into a market outside of the LMI Country **where Licensee has introduced or will introduce** a Licensed Product and where Regents’ Patent Rights exist [...]. [Click for full text.](#)*