WEBINAR

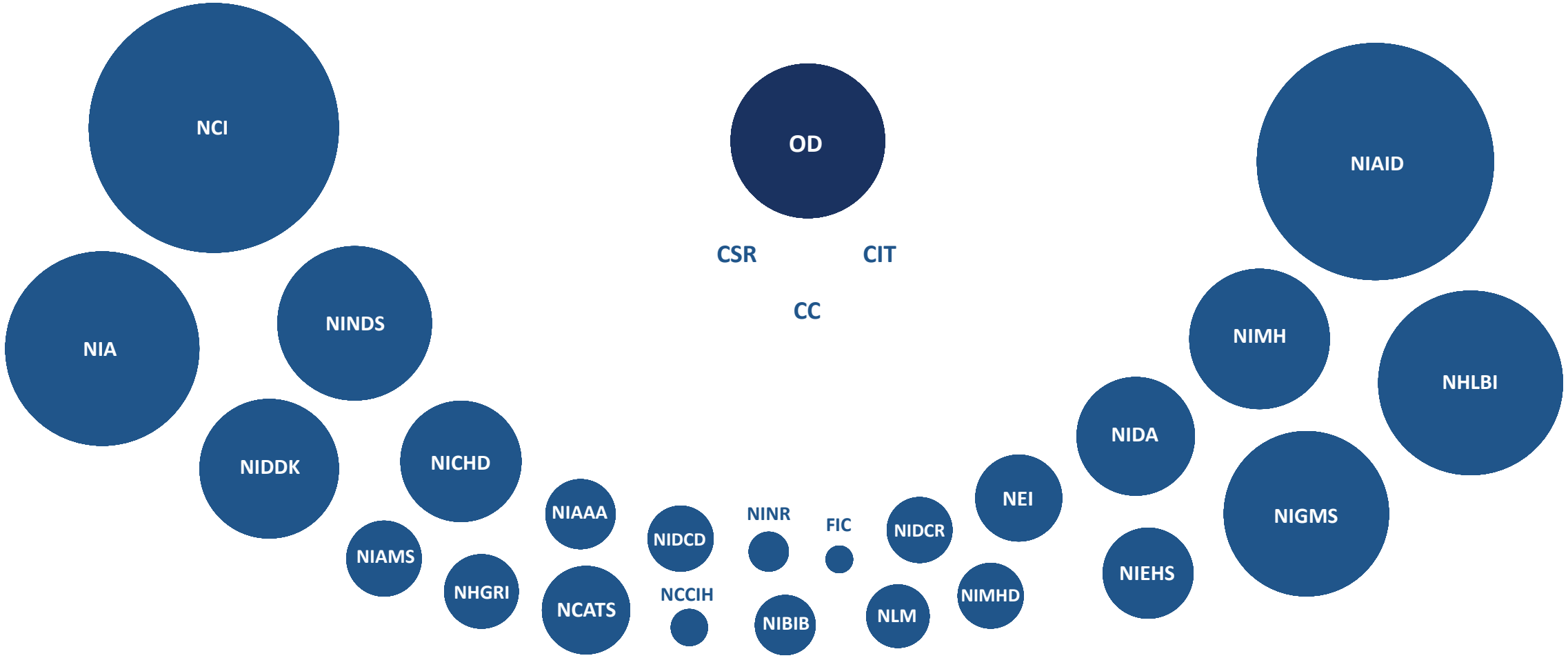
DRAFT NIH IRP POLICY: PROMOTING EQUITY THROUGH ACCESS PLANNING

JUNE 11, 2024

MISSION

NIH is the steward of medical and behavioral research for the Nation. Its mission is to seek fundamental knowledge about the nature and behavior of living systems and the ***application of that knowledge to enhance health, lengthen life, and reduce illness and disability.***

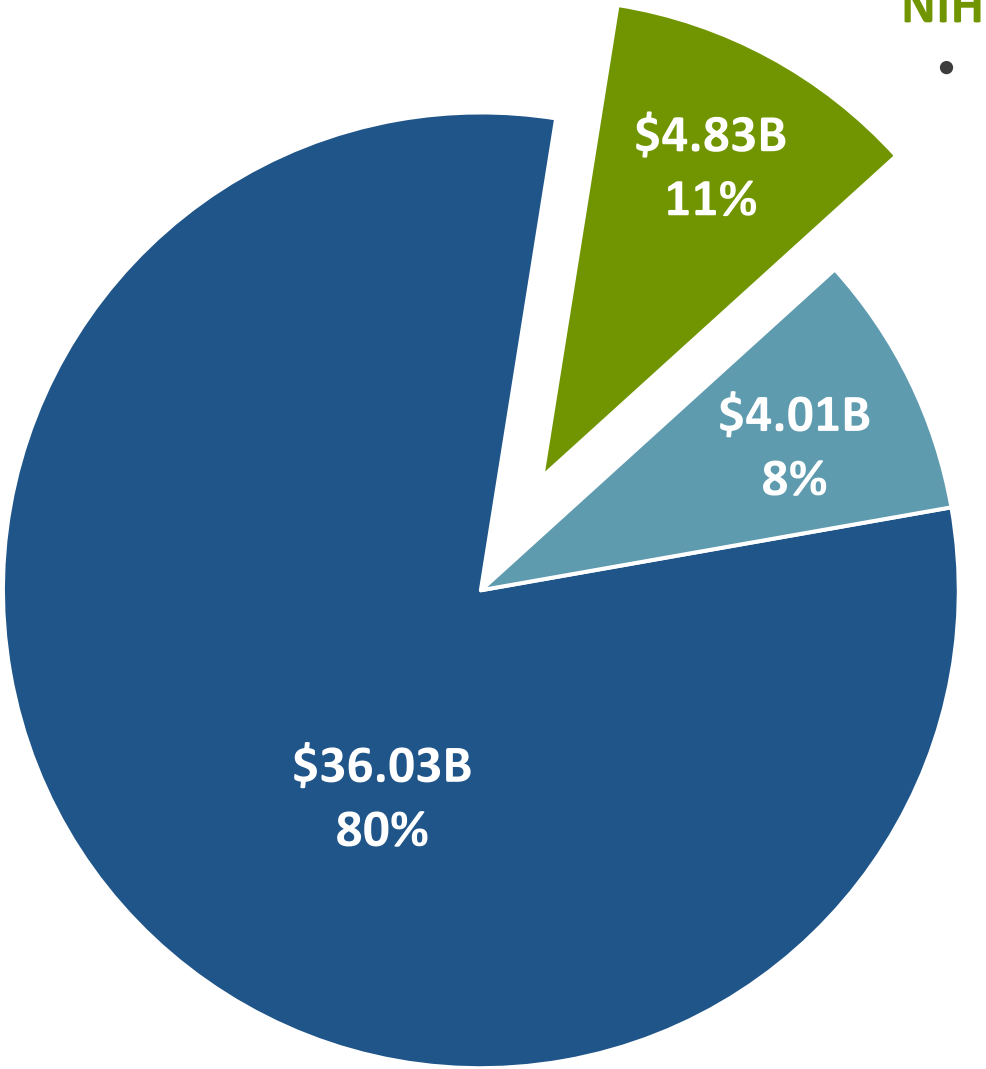
NIH: Legally Decentralized but Functionally Integrated



Budget & Funding

NIH Intramural Research

- Projects conducted by NIH scientists



FY 2022 Operating Plan

Other Spending at NIH

- Research management and support
- Other operational costs

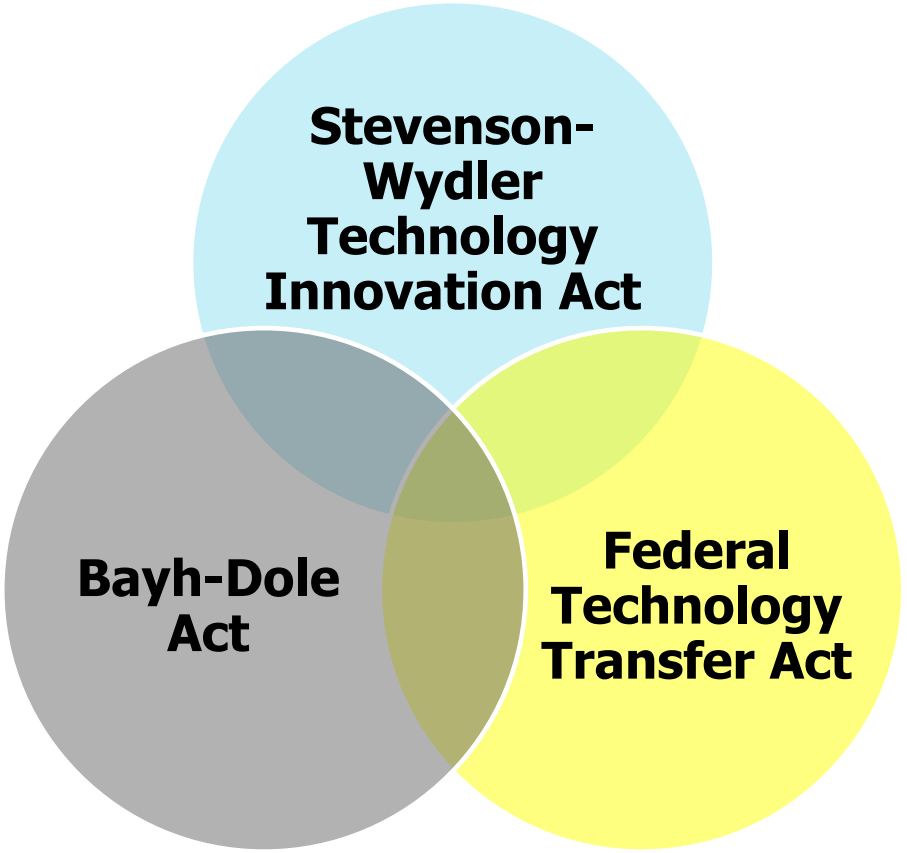
Spending outside NIH

- Research project grants at universities, medical schools
- Research centers
- Training

NIH Intramural Program (IRP) By the Numbers

FY 2023 Data

Legal Framework for NIH Licensing



- 35 U.S.C. § 207-209
  - Domestic and foreign protection of federally owned inventions
- 37 C.F.R. § 404
  - Licensing of Government-owned Inventions

Why Does NIH License Its Technologies?

- "[T]o promote the results of federally funded research and development through the patenting and licensing process." - 37 C.F.R. § 404
- What does this mean?
  - Utilize IP appropriately as incentive for commercial development of technologies
  - Attract new R&D resources
  - Obtain return on public investment
  - Stimulate economic development
  - **Benefit the public health**

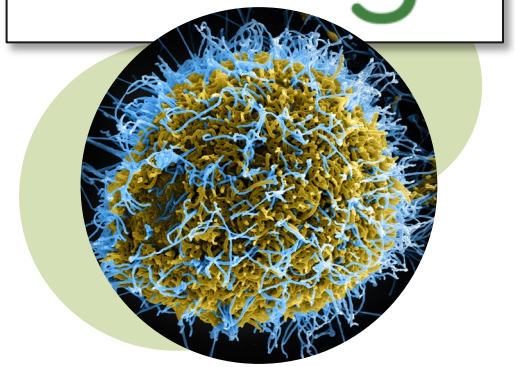
NIH Licenses Yield Substantial Public Health Benefits

- Broad range of technologies reflecting intramural program's diverse research
- More than 1,000 products brought to market
  - 46 FDA-approved vaccines and therapeutics
- Licensed IP utilized in over 1,200 clinical trials
- Over 60% of NIH licenses are for research tools
- Most licenses are non-exclusive

IRP Licenses Contribute to Novel Vaccines & Therapeutics

COMIRNATY®
(COVID-19 Vaccine, mRNA)

ebanga

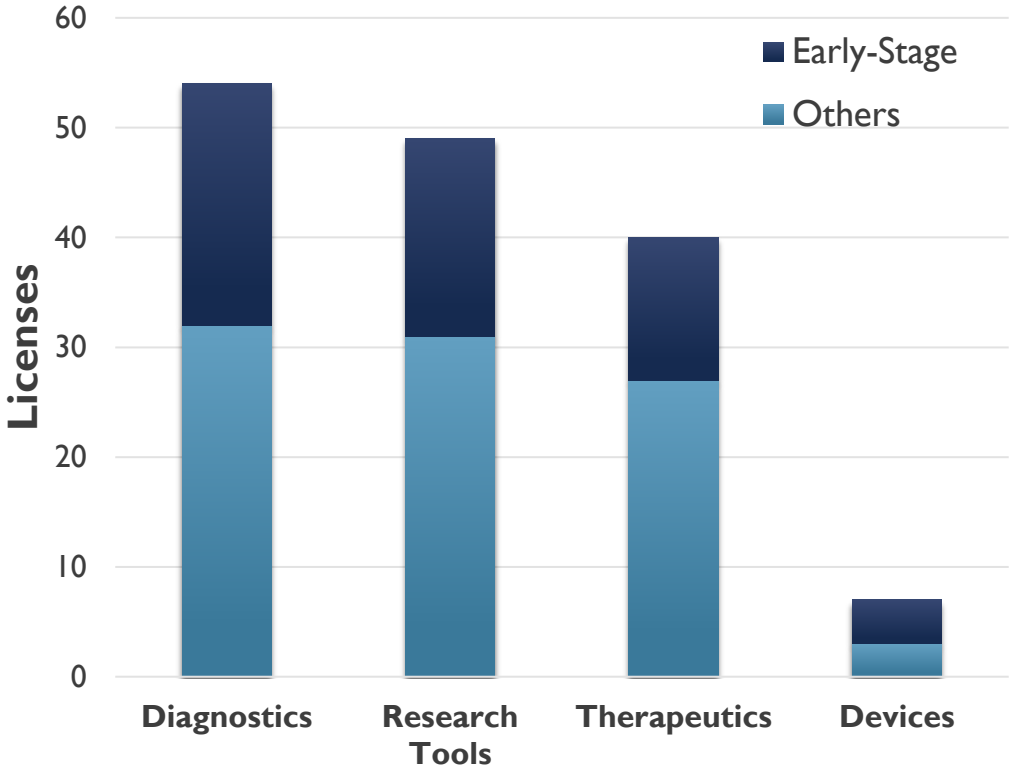


AREXVY
(RESPIRATORY SYNCYTIAL VIRUS VACCINE, ADJUVANTED)

Zokinvy®
(lonafarnib)
capsules 50 mg/75 mg

Abecma™
(idecabtagene vicleucel) SUSPENSION FOR IV INFUSION

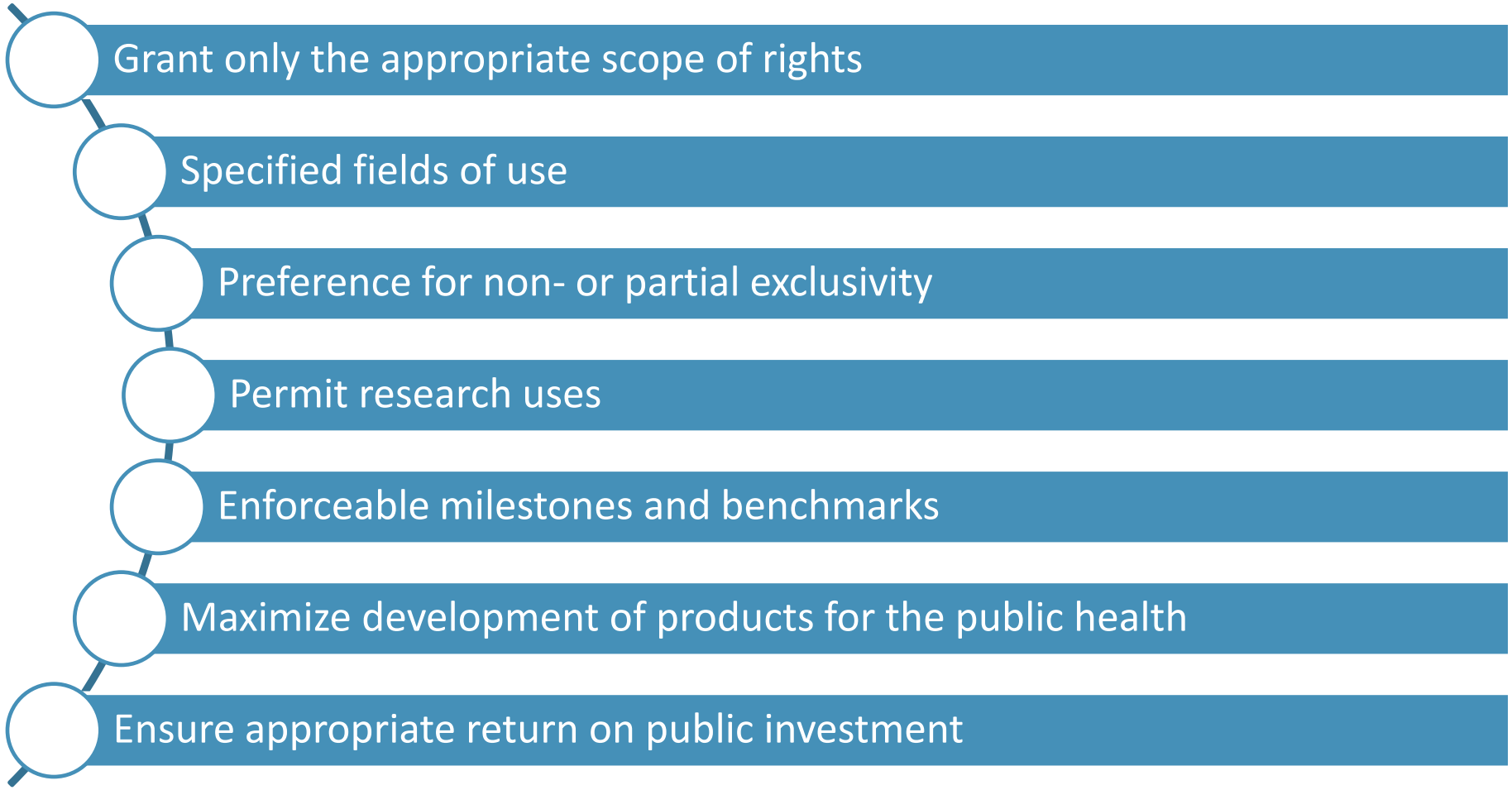
Who Licenses NIH Technologies?



- Not just big companies!
- About 1/3 of NIH's most successful technologies were licensed by early-stage companies.
- Overall, for every 2 U.S. licensees there is 1 foreign licensee.

Source: Public Health & Economic Impact Study of NIH Intramural Technology Transfer Licensing

NIH Licensing Principles



NIH Licensing Process

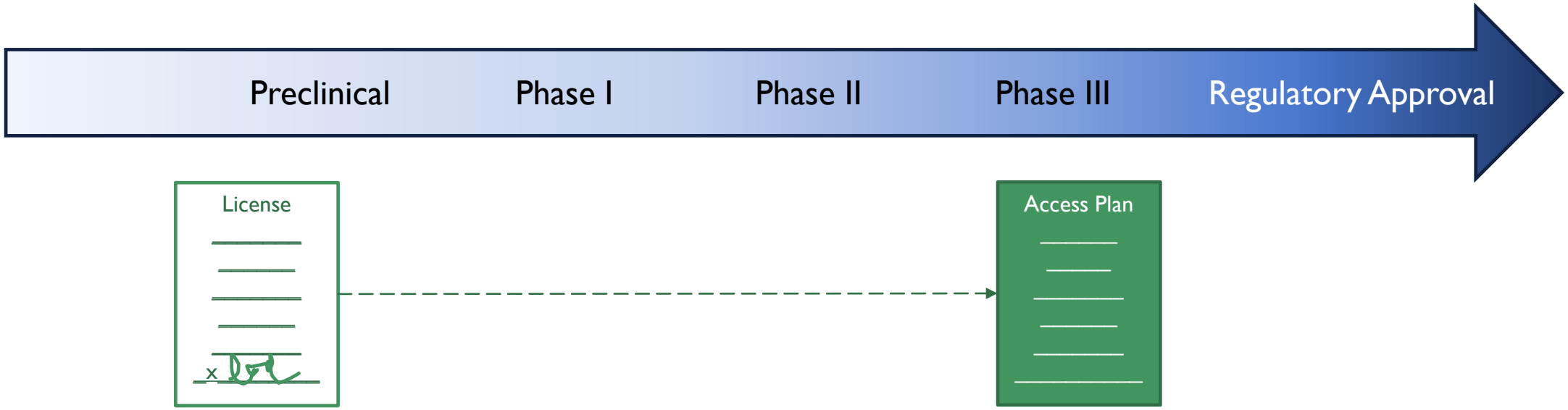
Negotiating the Terms

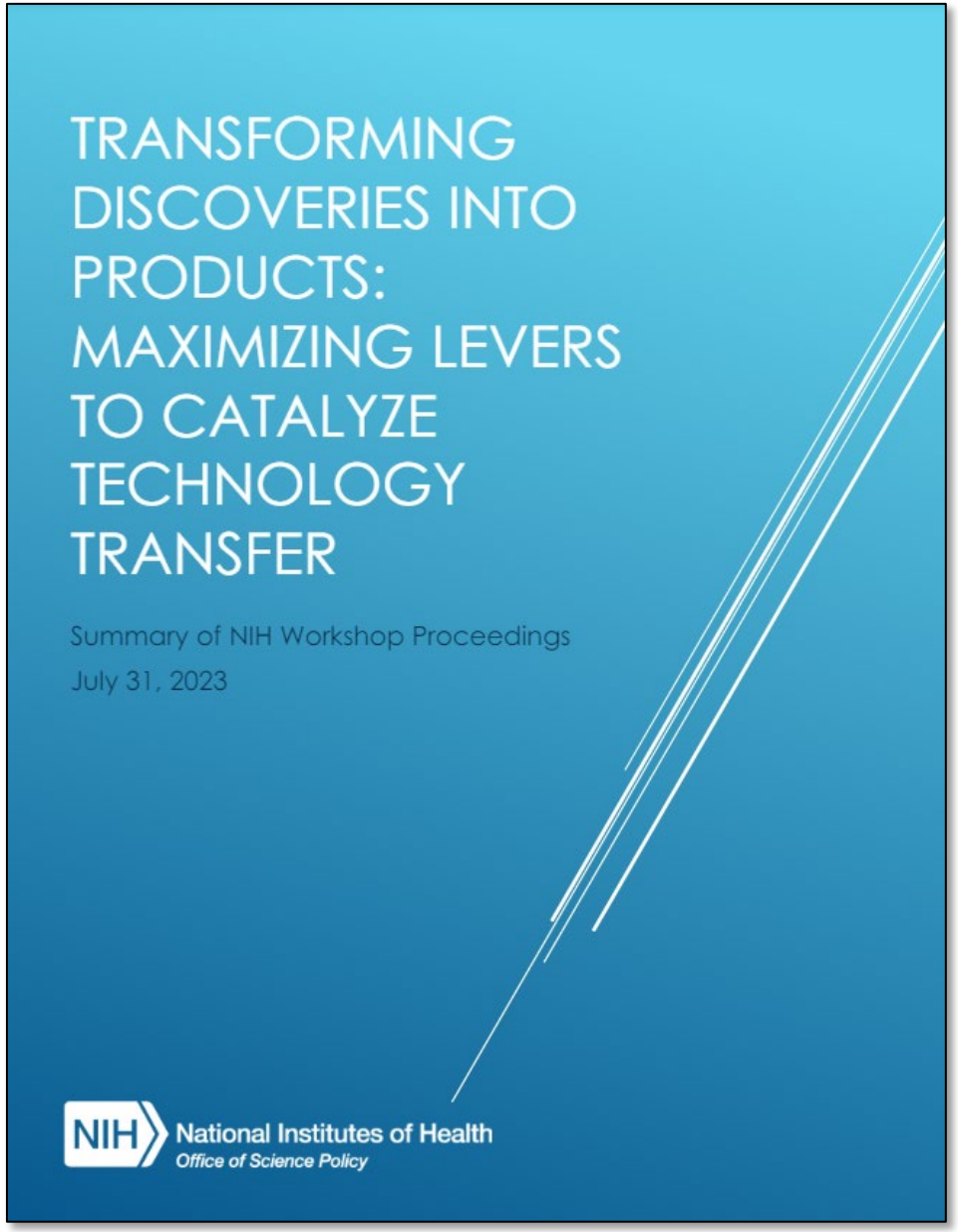
- Financials are just one part of the puzzle
- Scope of license grant (exclusivity, patents, products, territory?)
- Development timeline and associated benchmarks
- Reporting and other diligence requirements
- Sublicensing requirements
- Public benefit (“White Knight”) provisions

Tracking Licensee Progress

- Executing a license is the start of a multi-year relationship
- NIH has to ensure that the licensee holds up its end of the bargain
- How? Through periodic review of things like
  - Progress reports
  - Benchmarks
  - Payments
  - Review of public information
- License includes variety of levers for NIH to use if licensee is not performing

ACCESS PLANNING IN GENERAL





Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning

SUMMARY

- NIH is proposing to develop and implement a new policy within its **Intramural Research Program (IRP)** to promote access to products stemming from NIH-owned inventions.
- **NIH is seeking input on this draft policy and accompanying draft license agreement language that incorporates patient access in the commercialization process for NIH-owned inventions.**

THE NUTS & BOLTS

DRAFT, PROPOSED ASPECTS OF POLICY

PROPOSED POLICY SCOPE

- **Licenses originating from the NIH IRP within the following scope:**
  - Inventions made by investigators in the IRP and owned by the agency
  - Commercial patent licenses
  - Commercialization of drugs, biologics, vaccines, or devices
  - Exclusive, co-exclusive, partially excusive, or non-exclusive licenses

PROPOSED MODEL AGREEMENT LANGUAGE

- *"Access Plan" means Licensee's plan, and incorporating the plan(s) of its sublicensee(s), as applicable, that describes Licensee's strategy to support broad access to Licensed Product(s) for the U.S. population, as well as (a) through the lens of promoting equity for underserved communities such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality, as defined by Executive Order 13985 and/or (b) populations in low- and middle-income countries, as defined using the World Bank classification system.*
- *The Access Plan shall include, but not be limited to, a brief description of the Licensed Product(s); the anticipated patient population(s); other products, tools, facilities, or unique resources that would be necessary for use of the Licensed Product; and one or more strategies to mitigate access challenges across criteria including affordability, availability, acceptability, and sustainability. To the extent such Access Plan includes proprietary information [to be defined], upon NIH's request Licensee will also provide a non-confidential version or statement of such Access Plan that NIH may publish or otherwise make available to third parties.*
- *Within 3 months of a Licensed Product entering a first pivotal clinical trial (a Phase III trial or the equivalent), Licensee will provide NIH with an Access Plan (as defined), unless a written waiver or modification is obtained in advance from NIH. NIH agrees to consider such requests for waivers or modifications in good faith.*
- *Within 30 days of NIH's request (no more often than once annually), Licensee agrees to confer with NIH to review Licensee's progress, and to consider in good faith any reasonable modifications suggested by NIH with respect to the Access Plan.*

PROPOSAL TO DEVELOP GUIDANCE

- **Access plans would include include:**
  - Brief description of product(s)
  - Anticipated patient population(s)
  - Other products, tools, facilities, or unique resources necessary to use product
  - One or more strategies to mitigate access challenges (with examples)

- **Strategies to mitigate access challenges across criteria including affordability, availability, acceptability, and sustainability**

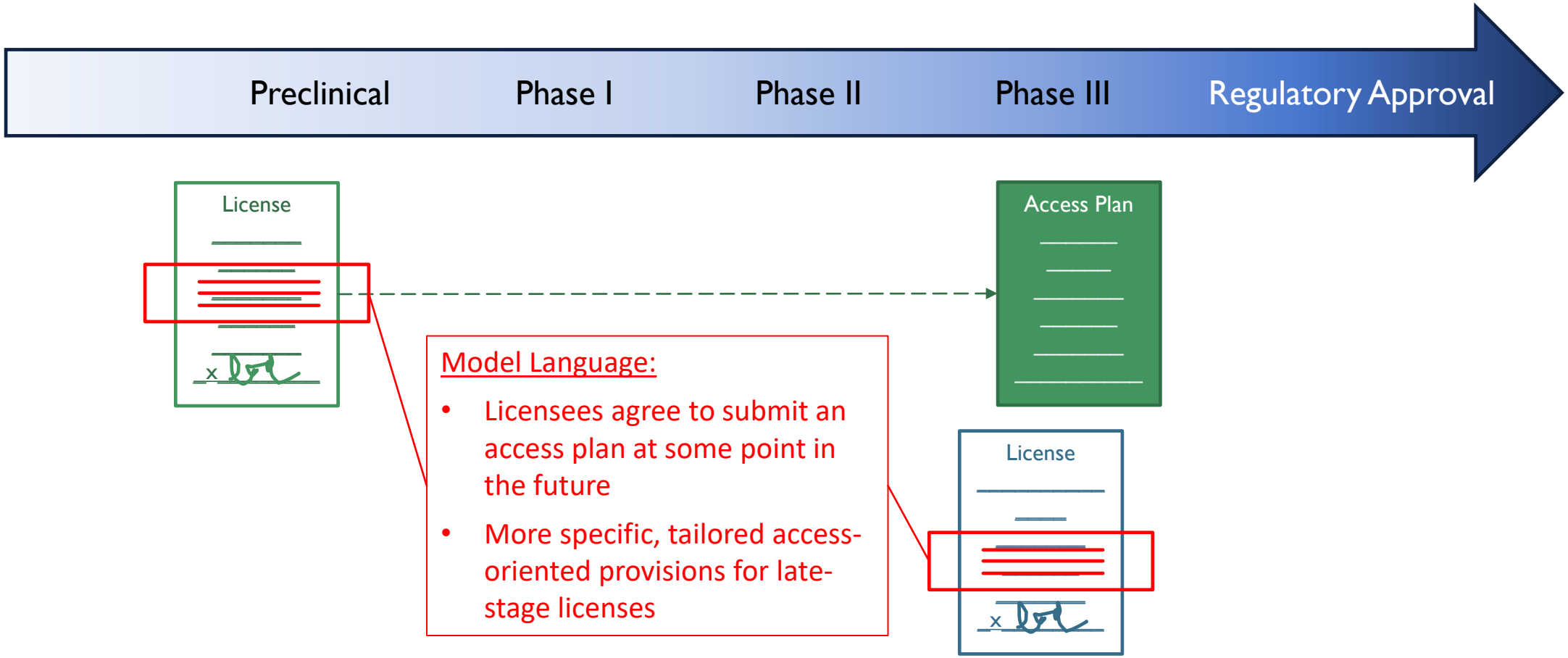
POTENTIAL STRATEGIES FOR EXPANDING REACH, BENEFIT

- Partnering with public health, non-profit, or patient advocacy organizations
- Addressing accessibility as a design objective
- Committing to sublicense relevant intellectual property and know-how
- Entering purchasing partnerships or commitments
- Submitting additional commercialization plans targeted to other markets
- Promoting equitable access and affordability in product development and deployment
- NIH/USG helping licensees achieve access goals

MYRIAD FACTORS AFFECT ACCESS

- **Affordability**
- **Availability**
- **Acceptability**
- **Sustainability**

ACCOUNTING FOR STAGE OF TECHNOLOGY DEVELOPMENT



PUBLIC ENGAGEMENT

REQUEST FOR INFORMATION

QUESTIONS FOR PUBLIC INPUT

- **NIH is seeking input on aspects of a draft, proposed policy (incl. model language)**

- **Additional input welcome on**
  - Promoting meaningful access approaches
  - Promoting transparency in the biomedical research enterprise and ROI
  - Providing flexibility while achieving clear policy objectives
  - Helping licensees achieve access goals
  - Establishing licensee obligations depending on the stage of technology development
  - Assessing policy impact

QUESTIONS

- **Request for Information:** Submit comments by July 22
  - **Federal Register:** https://www.federalregister.gov/documents/2024/05/22/2024-11188/national-institutes-of-health-nih-office-of-science-policy-osp-request-for-information-on-draft-nih
  - **Comment form:** https://osp.od.nih.gov/comment-form-draft-nih-intramural-research-program-policy-promoting-equity-through-access-planning/

- **NIH Technology Transfer Community Website:** https://www.techtransfer.nih.gov/
- **NIH Office of Science Policy:** https://osp.od.nih.gov/