EXAMINATION OF LEGAL AND REGULATORY PATHWAYS

for Management and Dissemination of Intellectual Assets Produced Under USAID Feed the Future Projects

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prepared by

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Note:
USAID is no longer an active entity. All references to USAID in this report reflect its role at the time of funding and publication.

Table of Contents

LIST OF ACRONYMS

ADS	Automated Directives System
AIDAR	USAID Acquisition Regulation
BDA	Bayh-Dole Act
BMGF	Bill & Melinda Gates Foundation
CFR	Code of Federal Regulations
CGIAR	Consultative Group on International Agricultural Research
CIMMYT	International Maize and Wheat Improvement Center
CIP	International Potato Center
COMESA	Common Market for Eastern and Southern Africa
DDL	Development Data Library
ECOWAS	Economic Community of West African States
EGS	Early Generation Seed
FAR	Federal Acquisition Regulations
GFSS	Global Food Security Strategy
IA	Intellectual Asset
ICARDA	International Center for Agricultural Research in the Dry Areas
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
IITA	International Institute of Tropical Agriculture
IL	Innovation Lab
ILCI	Innovation Lab for Crop Improvement
IP	Intellectual Property
IPR	Intellectual Property Rights
IRRI	International Rice Research Institute
ISRA	Institut Sénégalais de Recherches Agricoles
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
KARLO	Kenya Agricultural & Livestock Research Organization
MOU	Memorandum of Understanding
MTA	Material Transfer Agreement
NARES	National Agricultural Research and Extension Systems
NARO	National Agricultural Research Organization
NGO	Non-governmental Organizations
OA	Open Access
OPV	Open Pollinated Variety
PGFRA	Plant Genetic Resource for Food and Agriculture
PICS	Purdue Improved Crop Storage
R&D	Research and Development
REC	Regional Economic Communities
RODS	Research Output Dissemination Study
SMTA	Standard Material Transfer Agreement
TARI	Tanzania Agricultural Research Institute
USAID	U.S. Agency for International Development
USC	U.S. Code

EXECUTIVE SUMMARY

A. Introduction

Despite considerable efforts to promote innovation in the agricultural sector, a significant amount of technology either remains on the shelf or is not effectively scaled to reach its intended beneficiaries – the farmers and marginalized communities it is meant to support. This is true across publicly funded programs and projects, even though the U.S. Agency for International Development (USAID) and other donors prioritize striking a balance between fostering innovation and expanding stakeholder access to technology and innovation. Agricultural innovation has unique attributes and public good characteristics with distinct implications for technology management, dissemination, and scaling, especially in low- and middle-income countries.

The twenty-one Feed the Future Innovation Labs (ILs) managed under USAID's Bureau for Resilience, Environment, and Food Security (REFS) provide a uniquely suitable structure for examining the challenge of agricultural technology management and dissemination, due to their broad scope of crops, livestock, and policy areas, as well as their wide range of collaborating partners that could foster greater scaling of investments in agricultural technology. In particular, key scaling pathways and accompanying mechanisms and frameworks exist to disseminate agricultural technology, with gaps and challenges that could be addressed through legal approaches and coordination among partners. Based on legal analysis, interviews, and case studies, the study highlights common challenges in intellectual asset management and scaling as well as innovative dissemination strategies among the ILs, leading to recommendations on how to strengthen agricultural technology dissemination and scaling and suggestions for developing a tailored USAID policy on management of agricultural technology.

B. Study Objectives

The primary objective of this study is to assess how agricultural technological innovation developed by USAID-supported ILs is managed and scaled to reach local partners and end users to inform development of a USAID policy on agricultural Intellectual Assets (IAs). The aim of the proposed USAID guiding framework will be to ensure a balance between maintaining incentives for further innovation by ILs and their partners while fostering broad access to technologies. Such a policy framework must recognize the wide range of applicable technologies and different dissemination or scaling pathways for agricultural IAs as well as the role of intellectual property rights (IPR). Seeking IPR for agricultural technologies has different dimensions– it can fuel innovation and encourage dissemination but, depending on how it is managed, it can also limit opportunities for scaling due to the capacity and reach of the IL partner and the technology in question.

C. Background

At present, neither USAID nor university policies are designed to consider the unique nature of agricultural technology with regard to IA management and dissemination. Most agricultural technologies are not protected under formal IP, due in part to the fact that, in the agricultural sector, technology is not always clear-cut or easily marketable or commercialized. As such, agricultural

research and innovation tend to fall within the category of "public goods," which are central to addressing food insecurity in developing countries and require different strategies for their dissemination and uptake. The policy void has left donors without a clear system for tracking investment in agricultural technology and has put ILs and their partners in a position to determine individual dissemination strategies without benefitting from shared learning.

D. Legal Framework Governing Intellectual Assets Developed by Innovations Labs

The Bayh Doyle Act (BDA) and its implementing regulations lay the foundation to claim IPR on federally-funded technologies. This is complemented by the Automated Directives System Chapter 318 (ADS 318), which sets out the policies and procedures on intellectual property (IP) developed under USAID programs. Both the BDA and ADS 318 empower universities to claim ownership over federally funded inventions, provided that USAID is given a use right to those inventions. Universities' rights on the new invention are not absolute and are subject to certain rights and restrictions, such as invention disclosure, ownership, commercialization and licensing, and revenue sharing. Universities have their own policies on IP management, which are not specific to ILs, that govern technologies they develop. Overall, BDA, ADS 318, and university policies tend to prioritize commercialization of IP in specific sectors, such as engineering and pharmaceuticals, with little focus on agricultural innovation, which has left a policy lacuna for management of agricultural technology.

E. Innovation Lab Practices on Intellectual Assets Management and Dissemination

IL approaches to technology management and dissemination center around different forms of IAs[1] developed by ILs, their scaling pathways, and different legal and institutional considerations based on these factors, emphasizing the need for adopting a flexible approach to IA management and informing recommendations for Feed the Future crop improvement, research, and technology scaling programs.

Research and Development within USAID's Feed the Future is classified into three clusters: (1) plant and animal improvement research, (2) production systems research, and (3) social science research. Out of these three clusters, the main research outputs or technologies produced by the ILs fall within five key categories: (1) improved varieties, (2) research publications, (3) digital assets, (4) novel devices and processes, and (5) animal vaccines. Some IAs could be legally protected as patents (including plant patents), copyrights, or trademarks. ILs do not typically pursue IP protection but have done so in instances where the IA has high commercial value. USAID has also developed a Performance Indicator Reference Sheet (PIRS) framework for GFSS which tracks the progression of new or significantly improved technologies, practices, and approaches from R&D to

[1] Data on research outputs from the ILs was provided by the REFS for further analysis.

update by stakeholders, which has been useful for tracking outputs but is not nuanced enough to ensure effective dissemination.

Legal issues raise important considerations, both regarding technology development and dissemination, and they inform tools for dissemination used by partners (e.g., licensing agreements). For example, in the case of improved varieties, licensing agreements can be adapted to take into account the market for the crop or commodity (e.g., soybean vs. groundnut), type of crop (hybrid vs. open pollinated variety vs. vegetatively propagated crop), and scaling pathway (commercial, public, public-private, or community-based). Legal considerations may also relate to the type of technology (e.g., patent, plant breeders' rights, trademarks) or the partner (e.g., CGIAR Centers governed by CGIAR legal instruments). Lessons are aggregated across IAs and scaling pathways to form recommendations for a policy framework on scaling agricultural technology.

The main dissemination and scaling pathways for the ILs include: (1) commercial, (2) public, (3) public-private, and (4) community-based or civil society-based partnerships. Notably, however, many IAs are transferred in an informal manner. Commercialization is often pursued to fund further research, upscale technology, and create incentives for further innovation and investment by the private sector. Here, legal tools include licensing agreements and contracts. Public pathways can be pursued to deliver technology directly into the hands of farmers or to public sector partners themselves such as NARES; however, resource constraints are an ongoing concern. In this case, one of the main legal instruments is the Material Transfer Agreement (MTA) used by CGIAR Centers to transfer material to NARES. However, challenges faced by the NARES may require additional considerations. Under public pathways, dissemination to farmers may depend upon subsidy programs and extension services. Public-private pathways are common, since they leverage the reach and resources of the private sector to disseminate publicly developed material. MTAs are used at the CGIAR level, and licensing agreements are becoming increasingly prevalent tools used by NARES and, to an extent, CGIAR Centers. Community-based and civil society pathways depend upon local groups such as farmer's organizations, faith-based organizations and other non-governmental organizations (NGOs) to scale up or disseminate technologies; these are mostly informal arrangements. Illustrative case studies were also developed to highlight some of the opportunities and challenges associated with each of these scaling pathways, in addition to relevant legal considerations. These are summarized in Table 1 below.

F. Intellectual Assets Management Policies in other USG Agencies, Donors and Partners

The partners to which ILs transfer IAs – the private sector, CGIAR Centers, and NARES – may have their own rules and policies to guide the dissemination of the technologies received. On the private sector side, companies tend to seek opportunities in which there is sustainable demand for commercializing a technology and a market big enough to justify investment. Companies tend to seek exclusive rights in technology commercialization, mainly so that they can see a return on their investment in branding and promotion, although this can limit access to technologies that are deemed public goods.

On the public side, the main IL partners are international research centers (CGIAR Centers) and national research institutions (NARES). These public institutions have common objectives in agricultural technology dissemination, namely that both want to ensure that innovations have the greatest public good impact possible, although they differ in priorities and approaches. CGIAR Centers share common legal policies and frameworks, including use of the Standard Material Transfer Agreement (SMTA), but they often pursue different approaches to collaboration with the private sector and use of other legal instruments, such as licensing agreements. NARES focus on national systems and typically try to supplement scarce resources. Their objectives have intensified their interest in using legal tools for technology management, such as licensing agreements with the private sector. CGIAR Centers often engage directly with NARES to help disseminate technology, although practices vary by center, crop, and technology. Moreover, the current effort to unify existing CGIAR Centers under the One CGIAR initiative has led to ongoing work on harmonizing CGIAR Centers' policies regarding technology management, which provides important lessons for the research questions covered by this study.

Table 1: Scaling Pathways, Legal Considerations, and Illustrative Case Studies

Dissemination & Scaling Pathway	Process / Mechanism	Legal Considerations	Illustrative Case Study
Commercial	Private sector actors disseminate technologies (with high commercial value) to end users through markets.	Technologies with high commercial value are more frequently protected under IPR (patents, copyrights, plant variety protection, trademarks). Licensing agreements are often used to transfer technology to the private sector, which can attract private sector investment in IAs leading to wider dissemination. This approach can facilitate innovation in certain types of technology, but it can also leave out critical stakeholders with important development implications. The private sector will have an incentive to disseminate technology as long as it is commercially viable, but this may not reach underserved communities and farmers.	Soybean varieties developed by Soybean Innovation Lab (SIL) and International Institute of Tropical Agriculture (IITA) disseminated through licensing agreements with the private sector (varieties not protected under IPR).
Public Sector	Government programs (e.g., extension services, input subsidies) can be used to produce and/or deliver an innovation to end users. Other public approaches, such as the public good approach of the CGIAR, are also used to develop and transfer technology.	Dissemination and scaling of public goods involve different partners, including the NARES, and are covered under different legal instruments such as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGFRA), which has a strong focus on food security, and Material Transfer Agreements used by IL partners such as CGIAR Centers. These approaches recognize a broader pool of technology beyond IPR, since many of the IAs are treated as international public goods, and a role for an expanded set of partners. Challenges may arise in dissemination, which could be partially addressed by deeper engagement with the NARES and other partners.	Digital tools such as the Breeding Analytics Hub and QRLabelR as open-source platform from Innovation Lab for Crop Improvement currently used by NARES for selecting breeding traits suitable for local needs.
Public-Private Partnership (PPPs)	Both public and private sectors are leveraged to deliver innovations that meet public needs while ensuring efficiency, innovation, and sustainability.	Given private sector involvement, legal protection (IPR) is more often sought for certain innovations to incentivize private sector interest in the technology. A mix of legal instruments, e.g., licensing agreements, MTAs, can be used to disseminate technology to balance private sector interests with public good.	PICS bags produced by a private manufacturer and distributed with government support (subsidies and extension services) in several West African countries.
Community-Based	Community-based pathways use local groups to support the dissemination of technologies and behavior change practices.	Minimal interest in protecting technologies under IPR, although other legal instruments (e.g., licenses) may still be used.	New peanut varieties from Innovation Lab for Peanut being multiplied and distributed through grassroots initiatives supported by farmer groups and NGOs.

The study also surveyed the IP policies of relevant USG agencies, including the U.S. Department of Agriculture (USDA), Department of Energy (DOE), Department of Commerce (DOC), National Institute of Health (NIH), and the U.S. Department of Health and Human Services (HHS). These also build up on the BDA in terms of ownership and reporting requirements. Some agencies have provided for certain allowable clarifications of the BDA in their IP policies. For example, USDA and NIH have policies governing when an employee-inventor can retain title to IP, which can occur when a contractor waives title. Other USG agencies also have policies related to exceptional circumstances for modifications of funding agreements.

While these agencies fund research to benefit the public, they take an approach similar to the private sector in that policies focusing on commercialization and dissemination of IP are largely business-related. USDA, which also awards funding for agricultural research, has some notable good practices for the development and dissemination of agricultural innovations that could help inform USAID's policies in this area. One such practice is USDA's treatment of seed variety development and its work on determining related IP issues.

G. Key Findings and Recommendations

Below is a summary of key findings and recommendations emerging from the study.

Upstream Management of Publicly-Funded IP

- The upstream management of IP (and IAs) directly relates to downstream technology dissemination and scaling. However, legal instruments focus mainly on IP management at the level of the innovation itself without significant focus on dissemination. As this study has found, for agricultural technology, dissemination is often more critical than protection of the underlying technology, and legal considerations related to dissemination should be better integrated into IP/IA policies.

- The BDA is designed to encourage commercialization of innovation, mainly through patenting. However, this approach has limited application in the agricultural sector, where most innovations will not be covered under patents due to either the nature of the technology or the cost involved. As a result, commercialization of agricultural technology requires a stronger focus on dissemination pathways. As the study shows, even when there is a stronger commercial interest and role for the private sector, effective dissemination and scaling will depend upon collaboration with public sector partners, such as CGIAR Centers and NARES.

- At present, IAs and IP developed under Feed the Future projects are not managed or tracked in a coherent manner, with ad hoc approaches taken by the ILs and the universities that house them. Drawing lessons from these experiences, USAID policy could evolve to address gaps in current law, regulation, and policy in order to address this situation and the unique nature of agricultural technology.

- ADS 318, which sets out USAID's current policy on IP issues arising under USAID programs, is not sufficient to govern dissemination and management of agricultural IAs developed by

ILs. The scope of ADS 318 and BDA is limited to certain types of IP such as patents (including plants), copyrights, and trademarks developed and subsequently protected by USG funding recipients. ILs do not, generally, seek IP protection of IAs they develop; therefore, most IAs do not clearly fall under the scope of ADS 318 and the BDA. ADS 318 also does not contain provisions tailored to the dissemination of agricultural IAs.

- Because ADS 318 is applied on a contractual and case-by-case basis, there is no uniformity in USAID policy on management of IP. It may be argued that such an approach provides flexibility in negotiating IP terms in a funding contract, but it is limited in scope since ADS 318 only covers certain types of IP.

- It is clear, however, that USAID has use rights to the IP generated under USAID projects, but this does not address challenges with management of agricultural IAs. It is also possible that USAID's use rights could be compromised through the use of exclusive licenses, which may be preferred by the private sector in order to disseminate agricultural technology, whether protected by IP or not.

- Under regulation, USG's rights are limited to a use right on the technology developed and protected by a funding recipient as a result of their activities under USG contracts, and these use rights are not always well defined. However, USG partners have the right to elect title if universities do not meet relevant requirements and restrictions (on invention disclosure, election of title, and filing and maintaining of patent applications) as set out under BDA and ADS 318. It is not clear, however, how USAID would pursue this right, nor does it appear to be necessary that USAID expand its rights beyond a use right.

- Gaps exist under the BDA and ADS 318 that are often filled by IL host universities, which have comprehensive university-wide IP policies. These university IP policies are not specific to ILs but apply more widely to IP generated by universities employees and contractors, including ILs.

- University policies are mostly tailored towards commercialization of IP, which effectively leaves out some of the important IAs developed by the ILs and overlooks the public good nature of agricultural technology.

- A focus on IP also emphasizes a certain type of technology and dissemination pathway (commercialization), largely overlooking other dissemination pathways, which will likely be more applicable for agricultural technology. This is an issue for USG and university policies.

- IL host universities own all IPR produced by the ILs. All of the rights associated with management, ownership, dissemination, and transfer of the technology vest in the IL host university. If a host university does not pursue protection of the technology, it can request that the funding agency allow the inventor to elect title to the IP. Even when IP protection is sought, dissemination to underrepresented stakeholders may still be a challenge, since commercial goals do not always align with broad distribution. This could be at least partially

addressed through more specific USAID policy guidance on management of agricultural technology.

- University policies also differ across institutions, although they have to comply with the relevant federal laws. However, the gap in IP/IA policies related to federally funded agricultural technology has resulted in gaps in management of IAs produced by ILs.

Lessons Learned from IL Dissemination and Application to USAID Policy

- USAID thematic areas and phases of research (under the PIRS framework) provide a useful framework for tracking IL output; however, a more tailored approach to tracking ILs is warranted from a legal perspective. Many IAs developed by the ILs are in the form of social science research outputs, which take the form of knowledge products, including research reports, policy briefs, white papers, and peer-reviewed publications. Like other scholarly works, most of these knowledge products are governed by standard licensing agreements and publication contracts.

- USAID has increasingly stressed the need for open data and open access in their policies, and efforts are underway to enhance open access to peer-reviewed scholarly research resulting from federally-funded programs. This is in keeping with the requirement that all federally-funded research be publicly disseminated on an agency platform, such as USAID's Development Data Library (DDL). This public access requirement specifically excludes trade secrets, commercial information, or other proprietary data.

- ILs and their partners have varied dissemination approaches. These depend upon the type of crop (e.g., hybrid, open pollinated or vegetatively propagated), market characteristics (market size and growth, willingness to pay), and potential scaling pathways, which will lead to different legal considerations and structures for technology dissemination.

- Some of these pathways focus more heavily on IPR and private sector engagement, while others are more community focused. Integrating dissemination considerations into IP/IA management would help ensure that agricultural technology reaches the desired market and that a social, public good component is integrated to help address gaps in technology dissemination and scaling.

- Sometimes, ILs and their partners will obtain IPR for developed technologies prior to transfer, as this enables them to trace how, where, and by whom the technology is used. IPR may also help attract greater interest from the private sector to scale and commercialize the technology. However, this is not the norm across ILs, which often transfer unprotected IAs rather than formally registered or claimed IPR due to the nature of the technology developed. Even when legal tools like licensing agreements are used to engage the private sector, these are not often based on IPR.

- Technologies that have higher potential for commercialization (commercial seed varieties, trademarkable storage products, vaccines, etc.) tend to generate more interest from the private sector, which takes a business-focused approach to dissemination and scaling.

However, to protect their investment in branding and promotion, the private sector often seeks exclusive rights over technology, which can limit public access.

- Transfer of agricultural IAs through exclusive licenses can limit access of such technologies from intended beneficiaries like farmers and marginalized groups. Semi-exclusive/limited exclusive licenses could be considered instead, as they do not restrict the role of public actors such as NARES.

- Some IL partners, like NARES, play a critical role in technology dissemination. Engaging NARES in IA management (e.g., dissemination of improved seed varieties through licensing) can be invaluable for ensuring that technology reaches farmers and vulnerable communities. However, most NARES face particular resource challenges that limit their ability to claim and maintain IP and manage licensing programs due to staffing constraints and uncertainty over donor funding and government resource allocations. These constraints could be addressed at least in part through a policy approach to ensure that NARES are central to technology dissemination associated with federal funding, which may necessitate limitations on licenses with the private sector.

- For the CGIAR, another important IL partner, most assets are in the form of IAs and not formally claimed or registered IP. This is largely due to CGIAR policies and legal framework. As part of this framework, CGIAR Centers are not able to enter into purely exclusive licenses with the private sector and must put some limitations on these arrangements. CGIAR practices are evolving, as CGIAR Centers also contemplate how best to manage their IAs and make sure that they reach their intended beneficiaries. However, dissemination challenges and engagement with local partners likes NARES will still need to be addressed.

- ILs have noted knowledge gaps and financial challenges in dissemination of their technologies, which could be addressed by USAID.

Practices of Other USG Agencies, Donors, and International Partners

- Some USG agencies expand on BDA ownership provisions, such as in the case of contractor/employee-inventor title election, ownership rights modifications, waiver of title, or USG march-in rights, in order to align the BDA with the agency's own policies on IP ownership and dissemination.

- The USDA IP policy also specifically addresses agricultural innovations, such as plant and seed varieties and animal vaccines, filling a gap under the BDA and other instruments which take a more limited view of covered technologies. Further, a Working Group on Competition and Intellectual Property was established by the USDA to discuss IP issues relating to seed variety development.

- Several agencies have in-house technology transfer offices, which may also deal with technology developed by external researchers who aid in the dissemination of federally-funded innovations, albeit primarily through commercial pathways. The National Institute of

Standards and Technology (NIST) has additional tools for in-house labs, including a Lab-to-Market initiative.

- USG policies on IP management and commercialization could be developed to include detailed guidelines for contractors to create their own plans for dissemination, subject to approval by the funding agency, which could take into account different dissemination pathways. Examples to draw upon include DOE's guidelines for the creation of an IP management plan and NIST's IP management overview, which provide guidance for contractors to strategically disseminate their research. These examples could be tailored to take into account the unique nature of agricultural technology and the findings relevant to ILs and their partners, particularly with respect to the importance of different dissemination pathways and partners.

- CGIAR Centers have adopted comprehensive monitoring and evaluation systems that could be looked to as good practices. For example, the CGIAR publishes an annual CGIAR IA Management Report pursuant to the CGIAR IA Principles. Some NARES, such as the Kenya Agricultural and Livestock Research Organization (KALRO) and South Africa Agricultural Research Council (ARC), also do stocktaking on their IAs, particularly those that are protected or could be protected by IPR. If such stocktaking were integrated into USAID policy, it could be beneficial for tracking IAs developed under federal funding and assessing how commercial interests are pursued alongside public good dimensions.

- The Bill and Melinda Gates Foundation (BMGF) has acknowledged that IP protection is sometimes needed to ensure broad access to technologies. If it furthers the foundation's organizational goals, BMGF will require a non-exclusive, royalty-free license in the external background IP (humanitarian license). As long as it does not interfere with the scope of the humanitarian license, BMGF will also allow certain limited exclusive licenses. Although they are still developing their licensing policy, BMGF's IP policy serves as a good model for USAID because it attempts to balance IP protection and commercialization with a global access strategy. It is important to note that there are some limitations on exclusive licenses, which is also in line with CGIAR practices.

Areas for Further Development and Study

- All of the findings and recommendations summarized above could form the basis for a comprehensive USAID Policy on Funded Agricultural Technology Management and Dissemination. A draft policy guide could be developed in annotated format, which could be used by other USG agencies as well and customized as appropriate. A new training module for agricultural innovation dissemination strategies could also be developed to add to the Federal Laboratory Consortium for Technology Transfer's learning center. Legal tools could also be created to assist ILs and their partners.

- Some elements will require further investigation, including data rights and artificial intelligence where both law and practice are in flux and rapidly evolving. In particular, USAID should develop policies regarding the ownership, management, and accessibility of data inputs, datasets, and data tools by local partners. Even though USAID is not authorized

to regulate AI, it could still develop best practice guidelines regarding AI ownership and management, including contingency plans for AI database monitoring. These will be particularly important to agricultural technology dissemination in the future and to striking a balance between innovation and the interests of underserved communities.

- USAID is uniquely positioned to bring together major donors and key partners to design and establish streamlined guidelines for managing public good IAs in agriculture. Such harmonization could reduce conflicts over legal frameworks for technology transfer and enhance local partners' ability to disseminate agricultural technologies effectivity, ensuring that efforts align with practical needs on the ground and diverse donor policies.

- Although USAID currently uses the PIRS within the GFSS as a framework for tracking the development and progression of new or significantly improved technologies, practices and approaches, the current framework does not adequately address the complexities associated with managing IAs. USAID could explore ways to modify its MEL systems to also track the management and utilization of IAs for each innovation. This could help ILs better track IAs once they have transitioned to external partners ensuring that the innovations it supports are effectively managed and scaled.

INTRODUCTION

The U.S. Agency for International Development (USAID) and its Feed the Future initiative under the Bureau for Resilience, Environment, and Food Security (REFS) has funded and supported agricultural research and development through twenty-one Innovation Labs (or ILs),[2] which have generated a range of innovative technologies. ILs are part of research investments made by USAID and draw on the expertise of U.S. universities and partner country research and academic institutions to develop, disseminate, and scale technologies to combat food insecurity and climate change.[3] The U.S. government (USG) also supports IL partners including CGIAR Centers, National Agricultural Research Centers (NARES), and private sector actors. ILs and their partners are part of the Feed the Future initiative's focus on ending global hunger by cultivating new developments in agriculture, improving nutrition, and increasing food security.

ILs play an important role in bringing agricultural research to smallholder farmers and marginalized communities in Feed the Future countries. ILs generate many Intellectual Assets (IAs), some of which legally qualifies as Intellectual Property (IP), including crop varieties that improve food and nutritional security in low-income countries. IAs encompass any results or products of research and development activities of any nature whatsoever, including, but not limited to, knowledge, publications and other information products, databases, improved germplasm, technologies, inventions, know-how, processes, images, software, artificial intelligence systems, and distinctive signs, whether or not they are protected as IP. Most ILs do not seek intellectual property rights (IPR) for their technologies, although some ILs have sought IPR for technologies that have commercialization potential. The technologies developed by ILs, and their partners are transferred, disseminated, and scaled to promote their availability and accessibility by the intended users, namely farmers and consumers; however, these technologies are not reaching their targeted users at the desired rate.[4]

USAID does not have a clear policy in place to guide ILs and their partners on the management and dissemination of agricultural technology developed with USAID support and funding. The U.S. Government Global Food Security Strategy (GFSS) is the main guiding instrument on the pathway for agriculture-led economic growth, but it does not go into detail on management of IAs. The GFSS sees the uptake of technologies as a critical step to drive improved food security and nutrition and increased resilience, noting that agricultural research and development (R&D) are essential to meet the challenges of food insecurity, poor nutrition, environmental challenges, and biodiversity in a

[2] "Feed the Future Innovation Labs," Feed the Future: The U.S. Government's Global Hunger and Food Security Initiative, accessed August 22, 2024.

[3] "Snapshot: Feed the Future Innovation Labs," Feed the Future: The U.S. Government's Global Hunger and Food Security Initiative.

[4] "Feed the Future Innovation Labs."

country.[5] These are key drivers of sustainable economic transformation.[6] Dissemination and scaling of agricultural technology is a major objective in GFSS projects, but this notoriously difficult task is often referred to as the "chasm" or the "valley of death," as technologies developed in academic or other research institutions often fail to reach the market.[7] USAID policy guidance can be critical for striking a balance between encouraging innovation and ensuring that maximum benefit goes to underrepresented communities, smallholder farmers, and consumers in developing countries. The aim of this study is to highlight findings and recommendations that could contribute to a USAID guiding framework for maintaining incentives for further innovation by ILs and their partners while fostering broad access to technologies.

1.1. Unique Nature of Agricultural Technology

Many improvements in agricultural technologies are incremental and often build upon existing and publicly available technologies. For example, crop variety traits such as drought tolerance and disease resistance are often stacked on existing (and publicly available) varieties. Under these conditions, attribution of marginal contribution to the final product is often complicated. The incremental nature of agricultural innovations poses challenges for IP management. Traditional IP frameworks, which are designed for discrete, novel inventions, may not adequately capture the collaborative and cumulative nature of agricultural R&D. This distinction necessitates more flexible IP policies that can accommodate incremental innovations and ensure fair attribution and benefit-sharing.[8]

Agricultural innovations often need to be tailored to the specific agro-ecological conditions and the unique needs of local farmers and communities. This adaptation process is crucial for ensuring that the technologies are effective and sustainable in diverse environments. For example, a crop variety developed in one region may require modifications to thrive in another region's climate, soil type, pests, and diseases. Local adaptation ensures that technologies are relevant and practical for end users, which is essential for widespread adoption and impact. To adapt technologies locally, extensive field testing and development are necessary. This involves conducting trials under local conditions to assess performance, identify potential issues, and refine the technology. Local research institutions, agricultural extension services, and farmer cooperatives often play a critical role in these testing and development efforts, providing the necessary expertise and resources.[9]

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[5] "U.S. Government Global Food Security Strategy: Fiscal Year 2022-2026," Feed the Future: The U.S. Government's Global Hunger and Food Security Initiative, 74.

[6] T.S. Jayne et al., "Agricultural Productivity Growth, Resilience, and Economic Transformation in Sub-Saharan Africa: Implications for USAID," USAID, 2021.

[7] "Research Output Dissemination Study: Examination of Dissemination Pathways in the Use, Adoption, and Scaling of Research Outputs of Feed the Future Innovation Labs," USAID 5, July 2020.

[8] "Climate-Smart Agriculture," FAO, 2021.

[9] "IFPRI Research," *International Food Policy Research Institute (IFPRI),* 2021, www.ifpri.org; "Climate-Smart Agriculture."

The agri-food system is highly dynamic, influenced by factors such as agro-ecology, market demands, and policy changes. This dynamism necessitates flexible and context-specific partnerships and legal frameworks. For example, as climate patterns shift, crops that were once suitable for a region may no longer thrive, requiring ongoing adaptation and support from research and extension services.[10] While standard IP policies have been effective in managing high-value patents in fields like engineering and biomedical sciences, the unique features of agricultural innovations call for a more tailored approach. This includes recognizing the public goods nature of many agricultural technologies, the incremental and cumulative nature of agricultural R&D, and the need for local adaptation and flexible partnerships.

1.2. Study Framework and Research Questions

The study began with an in-depth analysis of the policy, legal, and regulatory framework that currently applies to agricultural IAs produced by ILs. This included analysis of U.S. federal law, USAID's policy on IPR, institutional policies of the host universities and relevant international law, all of which have an impact on IA management and dissemination. These are presented in Section 2.

The study also involved semi-structured interviews with key personnel from ILs, REFS, and other key stakeholders including U.S. Universities, CGIAR Centers, NARES, and other donors (See Annex 1 for list of key informants interviewed). To guide these discussions, the research team prepared questions on technology development, management, and dissemination by ILs and their partners, and each interview included the framing questions in Annex 2 and 3 along with more tailored questions that evolved over the course of the discussions. These interviews are referenced throughout the study and form the basis for some of the main findings and recommendations. The study was guided by the following interrelated evaluation questions:

1. What legal considerations (including whether or in what form to claim IPR) govern or impact the development and dissemination of agricultural IAs developed under USAID projects?

2. How is upstream management of IAs and IPR related to downstream scaling and transfer of technology?

3. What are the different types of agricultural IAs produced by USAID-funded partners (including ILs), and how are these scaled and disseminated?

4. What legal tools exist to facilitate (or hinder) the management and dissemination of agricultural IAs? How should these tools be designed with the unique nature of agriculture and the public good element of the IAs considered?

[10] "Optimizing Agricultural Management to Mitigate Climate Change Impacts," USDA Agricultural Research Service, August 11, 2021; "Rapid Response to Extreme Weather Events Across Food and Agricultural Systems (A1712)," National Institute of Food and Agriculture (NIFA), USDA, 2024.

5. What practices have been adopted by other USG agencies, implementing partners at universities, and partner institutions that could guide a USAID policy on management of agricultural IAs?

6. How can IL partners and development stakeholders improve the dissemination of publicly funded IAs to support food security and agricultural development?

7. How could a policy for management of agricultural IAs in Feed the Future crop improvement, research, and technology scaling programs enable achievement of Global Food Security Strategy Goals?

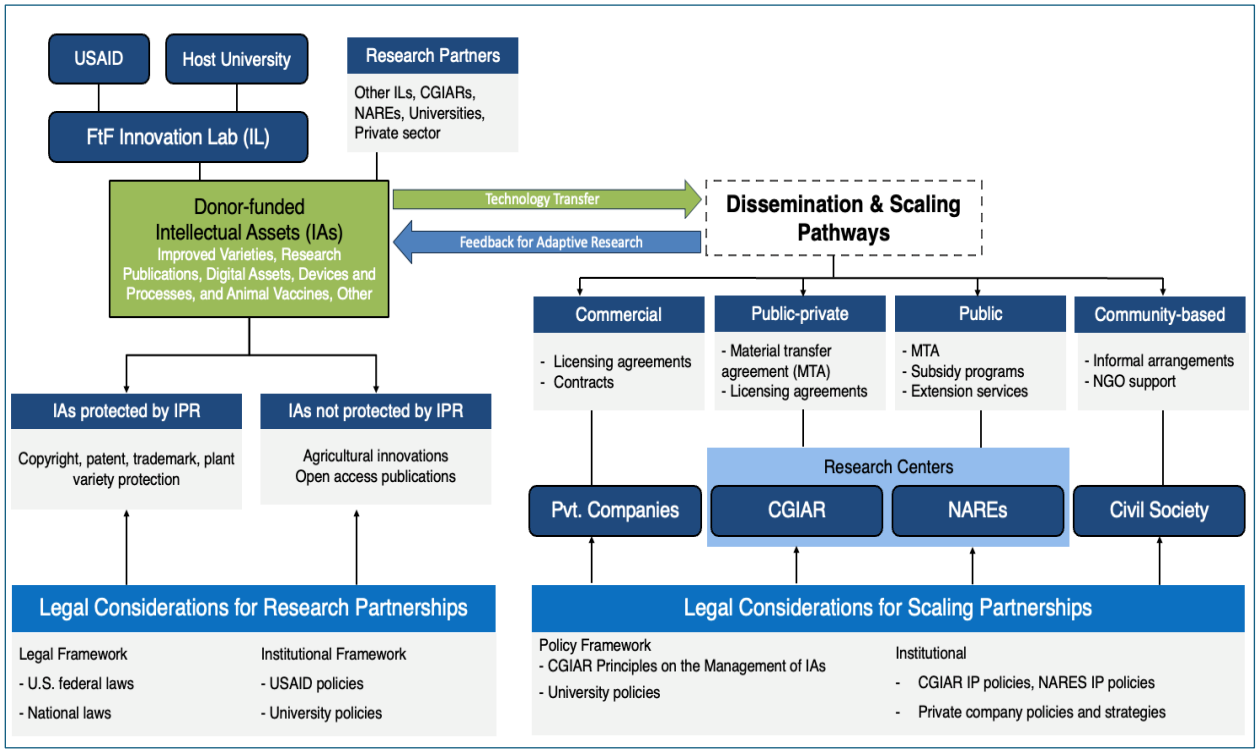
8. What related issues would require further investigation?

As the focus of this study, the Feed the Future ILs under USAID's REFS provide a uniquely suitable structure for examining the challenge of agricultural technology management and dissemination, due to their broad scope of crops, livestock, and policy areas, as well as their wide range of collaborating partners to foster greater scaling of investments in agricultural technology.

Examination of IL approaches to technology management and dissemination centered around different forms of IAs[11] developed by ILs, their scaling pathways, and different legal and institutional considerations based on these factors. These elements emphasize the need for adopting a flexible approach to IA management and also help inform recommendations for Feed the Future crop improvement, research, and technology scaling programs. These are summarized in Figure 1 below and elaborated upon in the sections that follow.

[11] Data on research outputs from the ILs was provided by the REFS for further analysis.

Figure 1: Intellectual Assets Developed by Innovation Labs, Dissemination and Scaling Pathways, and Legal Considerations



As illustrated in Figure 1, within USAID's three clusters of Research and Development under Feed the Future – (1) plant and animal improvement research, (2) production systems research, and (3) social science research – the main research outputs or technologies produced by the ILs fall within five key categories: (1) improved varieties, (2) research publications, (3) digital assets, (4) novel devices and processes, and (5) animal vaccines. Some IAs could be legally protected as patents (including plant patents), copyrights, or trademarks. However, ILs do not typically pursue IP protection but have done so in instances where the IA has high commercial value. These IAs are disseminated and scaled along four main pathways: (1) commercial, (2) public, (3) public-private, and (4) community-based or civil society-based partnerships. Legal issues raise important considerations both regarding technology development and dissemination, and they inform tools for dissemination used by partners (e.g., licensing agreements).

In commercial pathways, private sector actors (such as manufacturers, wholesalers, distributors, or retailers) make technologies available to end users (such as smallholder farmers, processors, or consumers) through markets. Here, upstream policies could provide some guidance on the management of IP, but these are not generally tailored to agricultural IAs. Public sector dissemination and scaling pathways often use government programs, extension services, and agriculture input subsidy programs to produce and/or deliver an innovation to end users. Here, there is not much guidance from upstream policies, as there is little market incentive to protect the technology. Public-Private pathways leverage the strengths of both the public and private sectors to deliver innovations that meet public needs while ensuring efficiency, innovation, and

sustainability. Here, policies of IL partner institutions such as CGIAR Centers and NARES are relevant. Community-based pathways depend on more informal channels and local groups such as civil society organizations, farmer organizations, or savings and loan groups to support the dissemination of technologies. Importantly, agricultural innovations tend to be considered "public goods," which are further developed through public funding by international and national research partners (CGIAR Centers and NARES). The end users of most innovations from ILs are smallholder farmers who often lack willingness or ability to pay for royalties. This has particular implications for U.S. federal laws and USAID and university policies, which are examined in greater detail in the section below.

Legal Framework Governing Intellectual Assets Developed by Innovations Labs

Understanding the management and dissemination of federally-funded agricultural technology must begin with the upstream legal and regulatory framework governing USAID and the universities that house the ILs. USAID's current policy guidance on IP can be found under Automated Directives System (ADS) Chapter 318 (ADS 318), which provides guidance on the ownership of IP generated under the agency's programs. This policy is integrated into individual agreements executed between USAID and its funding recipients. ADS 318 is based on the Bayh-Dole Act (BDA), which is a federal law governing the management of all technologies developed through funding from the USG. ADS 318 sets out rights and obligations of USAID, its funding recipients, and third parties in relation to IP developed under the agency's programs. Although ILs partner with universities around the world,[12] each IL is hosted by a U.S. university that has individual IPR protection and dissemination policies which govern IL practices. ADS 318, U.S. federal laws and regulations, and host university policies govern management of IA/IP in upstream phases of research which can impact downstream dissemination and scaling of technology. They provide some insights but do not specifically deal with IP issues relating to agricultural technology or its dissemination. Further, ADS 318 and U.S. federal laws and regulations do not take into consideration IP policies of the U.S. host universities.

2.1. U.S Federal Laws

The legal framework surrounding IP management of federally-funded technologies can be assessed through two lenses: (i) U.S. federal laws and (ii) USG-specific regulations/policies that address specific issues relating to IP management. All USG agencies are bound to follow U.S. federal laws concerning IP management, the main one being the BDA and its implementing

[12] "U.S. Government Global Food Security Strategy: Fiscal Year 2022-2026," 74.

regulations.[13] The BDA governs all technology funded by USAID and other USG agencies. USAID has integrated provisions of the BDA and its implementing regulations into ADS 318.

The BDA and its implementing regulations guide USG policies related to inventions made by non-profit organizations. BDA provisions apply to federal contractors, which are defined as "small businesses and non-profit organizations". Here, within the concept of "nonprofit," universities are included, since both Section 401.14 of the CFR and the BDA (Sec. 201(i)) define a nonprofit organization as a "university or other institution of higher education."[14] This means that the BDA also guides the policies of U.S. universities that host ILs.

According to the BDA, universities have the first option to decide whether to own, patent, and commercialize their inventions developed through federal financing support,[15] providing them with the option to "retain the entire right, title and interest throughout the world to each subject invention."[16] This means that the BDA gives contractors[17] (or universities in the case of ILs) the first right to pursue ownership of technology created under federally-funded programs without having to forfeit that right to the federal government.

Ownership rights of contractors are subject to certain conditions. The contractor must provide USG a "nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government."[18] The contractor must disclose any inventions to the relevant USG agency within two months of its internal disclosure and elect title within two years of the date in which the invention was disclosed to the agency.[19] The contractor must also file for patent application within one year of the date in which it decides to keep title over its inventions[20] and must periodically report on the utilization of the invention.[21]

Other restrictions on contractors include licensing obligations and payment of royalties to inventors. The BDA requires that nonprofit contractors share royalties with inventors and use the remaining balance for "scientific research or education."[22] Many U.S. universities have interpreted this to mean that part of the royalties can go towards the development and protection of other

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[13] 37 CFR §§ 401 and 404. The Bayh Doyle Act (BDA) can be found at 35 USC Ch. 18, within the Patent Act, and is implemented by regulation 37 CFR Part 401 (Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements).

[14] 37 CFR § 401.14; Bayh-Dole Act (35 USC § 201(i)).

[15] *See* 35 USC §§ 200-212.

[16] "Allocation of Principal Rights," 37 CFR § 401.14(b).

[17] Universities fall under the BDA as the interpretation of term "nonprofit," would include universities, since both Code of Federal Regulations (CFR) and the Bayh-Dole Act (35 USC §201(i)) define a nonprofit organization as a "university or other institution of higher education."

[18] Jennifer Plitsch, "Rights in Government-Funded IP: Changes May be on the Horizon," *Covington,* May 3, 2019.

[19] 37 CFR § 401.14.

[20] 37 CFR § 401.14.

[21] 35 USC § 202(c)(5).

[22] 35 USC § 202(c)(7)(C).

inventions from the university's community. Further, state universities must follow certain state law requirements on how to distribute royalties to their employees, including ILs. The USG is exempt from paying royalties to IP owners, because it retains a royalty-free license.[23] USAID policy elaborates that under a contract, royalties must not be excessive or inconsistent with the terms of the award. Further, a Contracting Officer may request information about royalty distribution.[24] According to FAR 31.205-37, which applies generally to USG contract provisions, royalties are allowable unless they are to be collected from the USG, which has a royalty-free license, or the patent is invalid, unenforceable, or expired.[25]

The BDA also gives agencies some options to control licensing and title under certain circumstances. A nonprofit contractor cannot assign rights in a federally funded invention without the permission of the agency, unless it is an entity that only manages inventions, such as a university research foundation.[26] There are also circumstances in which an agency may require licensing an invention to a third party if the head of an agency determines that it would be "necessary to achieve the practical application of the subject invention."[27]

In addition to the above-mentioned use right provided to the USG, the BDA sets out instances under which the USG can restrict or modify the contractor's rights**.** First, the federal agency (in this case USAID) could modify its funding agreement with the contractor in "exceptional circumstances" when the agency determines that restricting or eliminating the contractor's right to retain title will better promote policy and objective of the BDA. USAID does not elaborate on what "exceptional circumstances" would be in this case, but other federal agencies like the Department of Energy (DOE) do (see Section 4). Here, USAID could provide further guidance in relation to restricting title to agricultural IAs. Second, the BDA provides that USG agencies may exercise march-in rights where the funding agency may require the contractor to provide a license to a third party if the agency determines that it meets four statutory conditions set out in the BDA.[28] This is a controversial provision, and the USG has never exercised march-in rights. Further, march-in rights are restrictive, as the contractor has a right of appeal.[29]

While the BDA covers scenarios under which a contractor seeks to transfer its own rights to a third party, USAID does not elaborate or interpret these provisions in its ADS. As a prerequisite, funding recipients have to ask the Federal government for permission to transfer such rights.[30] It is important to highlight that, within the context of the BDA, there have been some concerns about

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[23] ADS 318.3.1.6.
[24] ADS 318.3.1.6; FAR 52.227-6.

[25] FAR 31.205-37; *see also* FAR Part 27, generally.

[26] 35 USC § 202(c)(7)(A).

[27] 35 USC § 202(f)(2).

[28] USG agency may exercise march-in rights if it determines that (1) a contractor has not undertaken practical application of the innovation, (2) there are health and safety issues that have not been addressed, (3) a contractor has not satisfied public use requirements, or (4) a contractor or licensee has not satisfied the preference for U.S. manufacturing requirement. 35 USC § 203(a).

[29] *See* 35 USC § 203(b).

[30] Tekila Gray and Sharon Lumpkin, "The Basics of Reporting NIFA Funded Intellectual Property," *National Institute of Food and Agriculture Planning, Accountability, and Reporting Staff*.

situations in which universities engage with private sector entities that aggregate patent rights for the sole purpose of enforcing patent protection.[31] In this situation, firms could hoard these patents and make money by suing any infringers, without properly applying or developing the actual invention. This would be contrary to the purpose of the BDA, which aims to promote the commercialization and application of federally funded inventions, as well as the intentions of USAID, which seeks to disseminate products for the public good.

Over the years, the BDA has succeeded in encouraging a significant increase in technology transfer through patents.[32] This is important for bringing certain technologies to the market and, ultimately, to end users who could benefit from them. One of the self-proclaimed benefits of the BDA is to allow for the licensing of federally-funded technologies to the private sector for further development or commercialization. An important goal of the legislation was to deliver technologies to end users through public-private partnerships.[33]

It is clear that the BDA has played an important role in boosting innovation; however, the BDA is mainly focused on certain forms of IP such as patents, which have limited application in the agricultural sector. Further, it has influenced universities to focus on commercial technologies that can generate revenue, as evinced in university policies (discussed below) and the move away from technologies that have a "public good" characteristic.

There are other federal laws of relevance. For example, the Federal Grant Cooperative Agreement Act (1977), provides guidelines on how government agencies should use their federal funds for assistance awards. For projects with universities, the Act mandates that the majority of the project administration must be performed by universities, which must meet certain requirements related to disclosing, reporting, and licensing inventions. With regard to USG agencies, they are limited to collecting and managing the information presented by the universities.[34] This limits USAID's role in IP/IA generated through ILs. Another important law to consider is the Stevenson-Wydler Act (1980), which was the first major technology transfer law. This act was amended by the Federal Technology Transfer Act (FTTA) of 1986, which established cooperative research and development agreements (CRADAs).

U.S. federal legislation, particularly the BDA, is significant, because it sets a foundation for contractors' (and universities') claims to IP developed with federal funding. It does, however, have notable gaps, particularly with respect to its lack of detail and the scope of IP explicitly covered.

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[31] Arti Rai and Bhaven Sampat, "Accountability in Patenting of Federally Funded Research," *National Center for Biotechnology Information* 30, no. 10 (2012):953-56.

[32] Comment of the United States Federal Trade Commission 9 (Feb. 6, 2024), Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 FR 85593 (proposed Dec. 8, 2023); *see also* John Miner et al., eds., "AUTM US Licensing Activity Survey: 2022, A Survey Report of Technology Licensing (and Related) Activity for U.S. Academic and Nonprofit Institutions and Technology Investment Firms," *AUTM*, 2022.

[33] *See* "Bayh-Dole Coalition Celebrates a Sustainable Future on World IP Day," Bayh-Dole Coalition, April 26, 2024.

[34] "Technology Transfer - Administration of The Bayh-Dole Act by Research Universities," GAO/RCED-98-126, Report to Congressional Committees, May 7, 1998.

Some of these gaps are addressed through other measures, including agency-specific regulations, although others are not.

2.2. USAID Regulations

In addition to the federal laws noted above, several U.S. agencies, including USAID and the U.S. Department of Agriculture (USDA) and U.S. Department of Commerce (DOC), both of which are Feed the Future partners, as well as the DOE, have their own regulations and approaches regarding IP management. Under current law and precedent, namely *Auer deference*, government agencies may clarify and interpret their regulations through policies and guidelines.[35] However, it is unclear whether recent Supreme Court decisions (Loper Bright and Relentless), which overruled Chevron deference, will also erode Auer deference in the future.[36] For now, it seems that U.S. agencies may continue to interpret their own regulations. USAID's regulations and practices, along with those of select USG agencies, are particularly relevant to this study (see Section 4 for more detailed discussion of other USG agencies' IP policies).

USAID's framework on how to manage IP and its other operations is established in the ADS.[37] Chapter 318 provides guidance on IP rights and IP issues that may arise during the planning and implementation of agency programs and operations.[38] The ADS is specific to USAID and contains the agency's operational policy and procedures for its programs. ADS 318 integrates several federal laws,[39] including the BDA and its implementing regulations[40] and closely follows BDA language.

ADS 318 has been applied to U.S. universities that receive federal funding, although there is no mention of universities in the policy. The ADS Glossary includes the term "Recipient" (of USAID funding), meaning "[a]n organization that receives direct financial assistance to carry out an assistance program on behalf of USAID, in accordance with the terms and conditions of the award and all applicable laws and regulations."[41] The scope of the term "Recipient" is expanded upon under ADS 318 Model Marks Clauses, and includes "implementing parties under a USAID grant or cooperative agreement and any other persons or entities receiving assistance as well as their

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[35] The *Auer* deference affords a federal government agency deference in interpreting a regulation it has promulgated. *See Auer v. Robbins*, 519 U.S. 452 (1997). The *Chevron* deference gives U.S. agencies the right to interpret statutes they are charged with implementing. Application of these standards should be monitored in light of recent Supreme Court decisions.

[36] *Loper Bright Enterprises v. Raimondo*, U.S., No. 22-451 (6/28/24) and *Relentless v. Department of Commerce*, U.S., No. 22-1219 (6/28/24); *see* Sean Lyness, "Chevron Deference's Demise Suggests Auer Won't Last Much Longer," *Bloomberg Law*, July 10, 2024; Lisa Nagele-Piazza, "Federal Agency Power to Interpret Regulations Remains Mostly Intact," *SHRM*, July 1, 2019.

[37] The ADS contains "the organization and functions of USAID [and] the policies and procedures that guide [its] programs and operations." "Automated Directives System (ADS)," *USAID*, last accessed August 23, 2024.

[38] *See* "Global Food Security: Improved Monitoring Framework Needed to Assess and Report on Feed the Future's Performance," United States Government Accountability Office, August 2021.

[39] This includes the Copyright Act (Title 17 of the USC), the U.S. Patent Act (Title 35 of the USC), and the Lanham (Trademark) Act (Title 15 of the USC).

[40] 37 CFR Part 401, which covers "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements."

[41] "ADS Glossary," USAID, September 2, 2021.

assignees, licensees, sub-awardees, and successors." The above provisions could be interpreted to include partnering universities as recipients acting on behalf of their ILs, since it refers to implementing parties of grants or cooperative agreements. Likewise, the definition is broad enough to include "any other persons or entities receiving assistance," which implies that ILs are also covered, as they are part of the covered universities. Finally, the definition refers to "assignees, licensees, sub-awardees and successors," which might imply that ADS 318 also applies to third parties who are granted a license or right over the innovations developed under USAID´s funding.

Similar to the BDA, ADS 318 provides that the contractor (or the funding recipient) receives the right to seek title over the IP, but this is subject to certain restrictions. Per ADS 318, the USG receives a use right to IP developed and subsequently protected by contractors under USG programs in the form of a non-exclusive, non-transferrable, irrevocable, and paid-up license. Some guidance can be found in the U.S. Code on how USG agencies can exercise the use right conferred under ADS 318.

The use right is in relation to "subject inventions," which are inventions "conceived or first reduced to practice in performance" of a contract or agreement.[42] BDA regulations provide some guidance on this, stating that if research activities, even if closely related, fall outside the scope of a USG funded project, prescribed USG rights do not apply.[43] An invention is not "conceived or first reduced to practice in performance" under a USG project if there is subsequent improvement of that invention using non-USG funds.[44] This means that USG use rights are restricted to inventions developed under a USG project, which could present a challenge for agricultural IA/IP that is incrementally developed with IL partners.

Title 15 of the U.S. Code states that "the government use license applies to inventions stemming from research partnerships with Federal Laboratories,[45] Federal employee inventions,[46] and federally funded inventions produced by contractors and grantees.[47] This includes inventions produced by ILs. It allows the government to use federally-funded inventions for its mission-driven purposes without a threat of legal challenges, especially for patent infringement.[48] The use license appears to apply to all USAID funding, regardless of funding level or co-development.

ADS 318 mainly provides guidance on three kinds of IP – patents, copyrights, and trademarks – extending its explicit scope a bit beyond the BDA but still remaining silent on certain forms of IP. In relation to patents, ADS 318 also specifically provides guidance for assistance awards to U.S. small businesses and non-profits (including universities). ADS 318.3.1.5, states the following:

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[42] 37 CFR § 401.1 (a).

[43] 37 CFR § 401.1.

[44] 37 CFR § 401.1 (a)(1).

[45] 15 USC § 3710a(b)(1)(A)).

[46] 15 USC § 3710d(a)).

[47] 35 USC § 202(c)(4)).

[48] "Return on Investment Initiative: Unleashing American Innovation," *NIST Special Publication 1234*, April 2019.

> Pursuant to 22 C.F.R. 226.36(b), assistance awards to U.S. small businesses and nonprofit firms should include 37 CFR 401.14. This provision allows the recipient to take title to subject inventions, subject *to certain rights and restrictions*, including providing the USG a non-exclusive, non-transferable, irrevocable, paid-up license to use, or *authorize others to use*, the subject invention throughout the world [emphasis added].

The inclusion of "certain rights and restrictions" means that USG assistance awards with universities must include clauses set out under 37 CFR 401.14, which provides a standard clause for the same use right to subject inventions as prescribed above with conditions on invention disclosure, election title, filing, and maintaining a patent right. This clause can be modified depending on the needs of the agency, as long as it is authorized under 37 CFR Part 401.[49] This provides that USAID can introduce alternative provisions in a contractor's funding agreement in multiples instances,[50] including when USAID determines under exceptional circumstances that the restriction or elimination of right to retain title to invention will better promote a policy objective prescribed in the BDA. The agency has certain standards and obligations to meet when exercising these modifications, and the contractor has the right to appeal the use of exceptions. Further, AD 318.3.1.1 (Patent Rights – General) provides that the USG has the right to use the subject invention for USG purposes, including allowing USG partners to use the IP for USG programs. This limits USAID's ability to guide dissemination and scaling of the technology.

ADS 318 also provides some guidance on copyrighted works. USG works can be copyrighted in other countries based on local laws and regulations.[51] Based on the type of data produced in copyrightable material, USAID rights in the data could be unlimited, limited, or restricted. Unlimited rights apply to data developed exclusively with USG funding. Here, USAID has the right to "use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so."[52] USAID receives a paid-up, non-exclusive, irrevocable, worldwide license with unlimited data rights. USAID can reproduce and use the data within the USG but may not disclose or manufacture data to the public with permission of the contractor.[53]

USAID has certain rights in federally-funded data or software and can negotiate additional rights on a case-by-case basis. If copyrightable materials include a contractor's proprietary information or product funded by non-USG sources, USAID must obtain additional rights before use.[54] These can include limited rights in previously acquired data or restricted rights in proprietary software. If a cooperative agreement contains a rights-in-data clause (FAR 52.227-14), which gives USAID an

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[49] "Use of the standard clauses at § 401.14," 37 CFR § 401.3(a).

[50] 37 CFR § 401.3(a).

[51] ADS 318.3.2.

[52] ADS 318.3.2.2, FAR 52.227-14 (a).

[53] FAR 27.404-2(c).

[54] ADS 318.1; "Limited Rights in Data," ADS 318.3.2.2(a)(2) & (3).

unlimited right in all data developed with USG funding, USAID will assume that it has an unlimited right in all data not marked as proprietary.[55] The rights-in-data clause also grants USAID a restricted right to computer software in the event the software was developed by a private enterprise and is financial, commercial, privileged, or copyrighted. USG cannot disclose this software outside the agency without prior permission of the contractor. USG can also reserve unlimited rights in copyrights for scientific and technical data using the rights-in-data clause. Though ADS 318 touches upon data rights of USG in copyrightable material developed under government contract, it does not expand on issues relating to protection of data, data privacy, ownership, or control of data which are becoming increasingly significant issues. Stakeholders consulted in the development of this study also raised concerns in relation to data collected. This is discussed further in Section 3.

ADS 318 provides some guidance on trademarks developed under USAID projects as well. However, this is mostly in relation to USAID's option to obtain rights to trademarks developed under USAID projects to protect its own interests in the United States or other countries. Here, USAID could transfer the right to use the trademark to the partner to use it on USAID's behalf. Issues such as trademark licensing have been highlighted by IL stakeholders as important to scaling of agricultural IAs; however, there is no support and guidance provided to ILs from USAID on this point. ADS 318 does, however, include a model clause that could be inserted into USAID assistance awards, which gives the USG a use right while holding the recipient responsible for use of license of the trademark by it and others.[56]

Important questions also arise downstream regarding USAID's use right, particularly if the IA/IP developed under a federally-funded program is subject to an exclusive license that gives another party unfettered discretion regarding the use of an innovation. While this question is not addressed in ADS 318, it is important, particularly given the inclination universities and ILs to pursue commercial distribution channels, where exclusive licenses will be more commonly requested. Allowing any exclusive right over agricultural IA may make it difficult for USAID to maintain its use right unless the terms are designed to make it very clear which rights are implied for which parties. In addressing this question, USAID may find it helpful to look at the licensing policy of the Bill and Melinda Gates Foundation (BMGF), discussed in Section 4, and CGIAR's approach to licensing. In both cases, limitations are placed on exclusivity in licensing, which could be beneficial for USAID to consider as well. These questions could be clarified in future USAID policy to avoid any possible conflicts.

While not mentioned in ADS 318, USAID funding recipients must fulfill the reporting requirements of the BDA through an online platform called iEdison, which is an interagency platform for BDA reporting hosted by the National Institute of Standards and Technology (NIST). Other USG funding recipients are also required to use this platform. The iEdison reporting requirement is mentioned in USAID's supplement to the Federal Acquisition Regulations (AIDAR 752.227-70) and seems to be incorporated contractually. On this platform, contractors upload administrative information

[55] ADS 318.3.2.1; ADS 318.3.2.2(a).

[56] "Model Marks Clause: A Mandatory Reference for ADS Chapter 318," *USAID*, March 16, 2010.

about subject inventions to iEdison, such as inventors, funding agency, brief descriptions, and public disclosure status, as well as title election and any patents filed.[57] This is different than the requirement that all federally funded research be publicly disseminated on an agency platform, such as USAID's Development Data Library (DDL),[58] which exempts the public disclosure of "trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law."[59] In relation to Feed the Future activities, USAID has also built, in consultation with Feed the Future partner agencies, a "Framework Needed to Assess and Report on Feed the Future's Performance," which serves "to guide performance monitoring for the initiative."[60]

2.3. Intellectual Property Management by IL Host Universities (Policies and Practice)

In line with the provisions of the BDA discussed above, many U.S. universities have technology transfer offices focused on IP management, which primarily manage patents and licensing activities. Over the past several decades, universities have become hubs for innovation, contributing significantly to sectors such as biotechnology, information technology, and engineering. In 2023, the National Academy of Inventors reported that the top U.S. universities collectively received thousands of utility patents, demonstrating their ongoing role in technological advancement and innovation.[61] Most high-value IAs (mostly patented) from universities come from a limited number of fields, such as engineering, biomedical sciences, computers and communication, and chemistry.

ILs do not have their own policies to manage the IAs they develop. Their IP management is based on the IP policies of the U.S. host universities that work as their management entity (the U.S. university is ultimately responsible for the conduct under the grant from USAID). Therefore, the IP policies of the universities that host the ILs are part of the legal foundation governing the relevant technology and its dissemination. These IP policies are university-wide and are not specific to the ILs. Like the BDA and ADS 318, most university IP policies focus on limited types of IP, primarily patents, and do not reference those that are common among agricultural technologies, such as plant breeders' rights (PBR)/plant variety protection (PVP) or localized methodologies, which have particular considerations. In practice, university systems prioritize certain types of technologies, particularly those in the medical industry, over agricultural technologies. One notable exception includes the University of Georgia, which has an Integrated Cultivar Release System that works with

[57] "About iEdison," NIST, effective August 8, 2022.

[58] In keeping with the Office of Management and Budget's Open Data Policy. "Memorandum for the Heads of Executive Departments and Agencies M-13-13: Open Data Policy-Managing Information as an Asset," Office of Management and Budget, May 9, 2013; "Supplemental Guidance on the Implementation of M-13-13: Open Data Policy – Managing Information as an Asset," *resources.data.gov*, accessed August 23, 2024; "Feed the Future Innovation Lab for Soybean Value Notice of Funding Opportunity," USAID 40, July 6, 2021.

[59] "Intangible Property," 7 CFR § 3019.36(d)(2)(i)(A); "Managing Public Access to Results of Federally Funded Research Policy," NIST P 5700.00, June 26, 2015.

[60] "Global Food Security: Improved Monitoring Framework Needed to Assess and Report on Feed the Future's Performance," United States Government Accountability Office, August 2021.

[61] "NAI Announces Top 100 U.S. Universities," National Academy of Inventors, September 12, 2023.

Georgia agricultural state agencies, as well as the university's research foundation and its College of Agricultural and Environmental Sciences, to provide IP protection, management, and marketing for plant breeding research and seed development.[62]

Host universities have the right to pursue ownership of technologies developed by the ILs. This right is conferred to universities under the BDA (which provides contractors the right to claim ownership over federally-funded technology) and ADS 318 (which implements the BDA through contractual arrangements). University policies provide further details on ownership of IP produced by university employees. University IP policies grant the relevant university both moral (e.g., claim of ownership) and economic rights (e.g., royalties) arising from inventions developed either (i) by individuals formally related to the university (either through employment, consulting or educational purposes) or (ii) through resources owned or procured by or through the university. How and whether each university seeks ownership over the relevant inventions seems to be determined on a case-by-case basis. The university, based on its own internal policies, may choose to apply for legal protection; however, this decision is often based largely on the commercialization potential of the technologies, as noted in their IP policies. This underlying priority of university IP policies does not fully consider the public good nature of agricultural technology or the full range of IAs developed by the ILs.

University policies can differ across institutions, and they exist independently of the USAID framework. However, universities policies have to comply with the federal laws set out above. Additionally, USAID policies are implemented through agreements with funding recipients (universities) which do explicitly reference the ADS. Like other funding recipients, universities also have reporting obligations. In some cases, university IP policies may provide additional guidance where the ADS is silent. For example, U.S. university policies provide for specific invention reporting requirements, while providing their own strategies for dissemination, often through commercialization.

The university policies surveyed include provisions on invention disclosure, ownership, commercialization and licensing, and revenue sharing. Some universities build in more specific procedures for dissemination and protection, while others have a generalized policy that seems to be designed for more flexibility.

Universities require their employees and faculty to disclose inventions to an IP unit or department, which then evaluates the invention for commercial potential. For example, Purdue University's office of research will determine whether to pursue commercialization of inventions within 180 days, after which the university's general counsel will determine the issue of ownership.[63] Michigan State's technology office also considers commercial potential. If it does not decide to pursue a

[62] "About Us: The 'Systems Approach' to Bringing Plant Materials to Market," Georgia's Integrated Cultivar Release System. Washington State, Mississippi State, and Michigan State also mention plant variety protection in their IP policies, but do not extensively deal with agricultural technologies as a whole.

[63] "Procedures for Disclosure, Assignment and Commercialization of Intellectual Property," Purdue University, effective July 1, 2015.

patent, ownership can be transferred to the inventor upon approval from a government sponsor (if using government funding).[64]

University IP units can sometimes be assigned ownership on behalf of the university and can also take steps to protect the IP. Universities usually use one of the following types of units to handle IP matters, including Bayh-Dole compliance: (i) centralized licensing office,[65] (ii) decentralized licensing office, (iii) foundation, or (iv) outside contractor.[66] Most commonly, among the universities surveyed, a university-affiliated non-profit, often called a "Research Foundation," handles IP protection, compliance, reporting, and, in some cases, commercialization.[67] This organization or Research Foundation is assigned the IP generated by ILs and the university community more broadly. Other universities handle IP through a series of campus offices that report to a vice president or centralized provost office.[68] Sometimes an additional technology transfer office handles licensing.[69]

The BDA and university policies provide nuanced guidance on commercialization of federally funded research. The BDA speeds up the commercialization process as it allows universities to retain IP to the technology and commercialize it. The university has the right to own IP developed by ILs subject to the condition that it pursues protection of that IP in a timely manner and as per the conditions set out in the BDA. Based on this, many universities specify in their IP policy that the intent of ownership is not only to compensate for resources used but also to promote commercialization and development of R&D.

Many university policies allow universities to license the IP to a third party if it will benefit the public and the university. For example, Michigan State University's licensing agreement generally includes a provision stating that the "licensee should diligently seek to bring the intellectual property into commercial use for the public good and to provide a reasonable return to the University."[70] The university has the right to pursue royalties for any IP that is licensed by the universities. With a licensing agreement, the licensee receives a revocable right to commercialize the technology or creation they received. The licensing agreement includes the terms and conditions for both parties with respect to the long-term use and commercialization of a technology, including the period of time, extent of monetary compensation and royalties, and the need for record keeping.

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[64] "MSU Patent Policy Handbook," Michigan State University, Section III.7, February 2020.

[65] Examples of this would include UC Davis' Innovation Access office, MSU Technologies at Michigan State, and Texas A&M Innovation. Other examples include Cornell University's Center for Technology Licensing, University of Mississippi's Office of Technology Management, and Washington University's Office of Commercialization.

[66] "Technology Transfer - Administration of The Bayh-Dole Act by Research Universities."

[67] For example, Kansas State University, the University of Florida, and the University of Georgia all have Research Foundations. Virginia Tech has an affiliated non-profit called Virginia Tech Intellectual Properties, Inc.

[68] For example, Purdue, Tufts, and the University of Illinois.

[69] For example, Penn State has a separate IP licensing office and University of Florida has an Office of Technology Licensing in addition to its Research Foundation.

[70] "MSU Patent Policy Handbook."

If a university determines that a technology does not have commercial potential, it will usually defer ownership to the inventor. In such cases, university-sponsored scaling and dissemination are limited by the goal of monetization, leaving many ILs that do not produce IAs with commercial potential with little to no guidance. Stakeholders also noted that university policies could conflict with dissemination practices at the IL level, as ILs sometimes encourage ownership to be vested in local partners. Some IL stakeholders emphasized that the lack of incentive models at the university level to disseminate the technology is a significant issue. This could be because universities are concerned about liability or reputational risk associated with dissemination and scaling.

IL host universities provide a university wide framework for management and commercialization of IP, including those developed by ILs. These policies are based on the BDA and funding contracts that reference the ADS; however, they provide additional guidance on reporting requirements, commercialization, and management of IP. Universities decide whether IP protection should be pursued for an IA developed by the ILs. This decision is based on the commercialization potential of the IA, which is not a priority of the IL. In some cases, universities have assigned ownership of the IP to a third party so they can prioritize its management. University policies focus on limited types of IP, mostly patents, and do not prioritize management and protection of agricultural technology.

2.4. Key Findings and Gaps

The policies and guidelines for managing IAs under federally-funded projects and by U.S. universities have been largely developed with high-value patents in key fields in mind. Given that technologies developed by ILs are governed by the same technology transfer offices under standard university policies, it is worthwhile to explore whether these rules and policies are fit for purpose. Agricultural innovations have several key distinguishing features that merit a more nuanced approach from USAID and university partners. There are several gaps in current policies in context of agricultural IAs developed under USAID projects that are relevant to a potential USAID policy on IA management and dissemination.

- The U.S. legal and policy framework provides some guidance on management of IP developed under federal funds; however, it falls short of addressing challenges in relation to management of agricultural IAs created with federal grants and issues arising in the context of dissemination and scaling, which are often more important in agriculture than questions of how to protect a technology itself.

- The scope of ADS 318 and BDA, which focus on commercialization of innovations, applies to USAID funding recipients (universities), but it is not sufficient to guide dissemination and scaling of agricultural IAs. Its scope is limited to IP protection such as patent, trademarks, and copyright; however, most of agricultural technology transferred by ILs are unprotected and appear to be a bit outside of the scope of ADS 318 and BDA.

- IP/IA management of agricultural IAs developed by ILs is approached in an ad hoc and noncoherent manner. This is either based on university policy under which ILs exclusively develop IP or deferred to IL partners such as CGIAR Centers and NARES, which have their own institutional policies.

- Many issues regarding IPR of subject inventions seem to be addressed on a case-by-case basis during contract negotiations for funding. Although this gives some flexibility to contracting parties to negotiate IP terms in funding agreements, the scope is still limited to ADS 318, which only covers patents, trademarks, and copyright.

- The only clear position regarding IP management is that USAID can obtain or retain use right to share materials under the contract or grant for government use,[71] but this provision does not seem to be adequate to guide the dissemination of agricultural technology developed through USAID's financial support.

- USAID has a use right to IP developed under USAID contracts; however, it can exercise advanced rights such as retaining title to a subject invention or assigning it to a third party if the funding recipient (the university in this case) does not meet certain obligations; however, it is unclear whether and how USG would do this. In fact, this may not be the most viable option, as exercising these rights has its challenges, and USG may have its own constraints in pursuing this option. As an alternative, USAID could require that its grantees/funding recipients meet additional requirements, such as reporting (including IA screening and IP capture, coordination and compliance requirements) in relation to management of agricultural IAs, so that it can pursue appropriate action.

- IL host universities have the first right to take title to IP developed with federal funding. These universities have their own priorities in pursuing IP, which may be based on commercial goals of the universities.

- Due to the unique nature of agricultural technology, much of the technology is not covered under IPR like patents and trademarks but falls instead within a broader category of IAs, which is not the focus of most existing university IP policies. As public goods with little or no commercial value, these agricultural innovations often receive scant guidance under U.S. federal laws, USAID policies and regulations, and university policies. Further, they do not tend to receive support from technology transfer offices.

- U.S. host universities tend to pursue commercialization for technologies developed in certain industries (like pharmaceutical or engineering) but do not have a coherent strategy for pursuing protection of agricultural technology developed with the public objective even if some of these technologies have commercialization potential.

[71] ADS Chapter 318 only states that, in the case of patents, a contractor may have the option to negotiate and then transfer additional rights to USAID via a license. ADS 318.1

INNOVATION LABS' PRACTICES ON IA MANAGEMENT AND DISSEMINATION

The primary goal of the ILs is to harness the expertise of top U.S. universities and developing country research institutions to tackle global challenges in agriculture and food security. This section of the report examines IL practices on IP development, management, and dissemination. Figure 1 above summarizes the main legal and policy considerations applicable to IL practices on technology development and IP management and dissemination. It is centered around the research partnerships where IL collaborate with other ILs, CGIAR, NARES, universities, and private sector actors to develop IAs. Relevant technologies, practices, and approaches developed by the ILs (along with the unique nature of agricultural IAs) are important, as are legal considerations relevant to the IAs. IL research partners such as CGIAR Centers and NARES also have overarching legal and policy frameworks to guide development, dissemination of scaling of their technologies. All of these relate to the scaling pathways (commercial, public, public-private, and community based) pursued by the ILs. Interviews with the ILs were conducted as a central component of the study, including questions focused on technology development, IP management, and technology dissemination.

3.1. Monitoring Technologies, Practices, and Approaches Developed by Innovation Labs

A key component of developing an IA/IP management strategy is to develop processes/procedures that could help identify IAs within the institution. ILs produce a number of agricultural IAs (including technologies, practices, and approaches) which have the potential to be scaled at a higher rate. For monitoring, evaluation and learning (MEL) exercises, USAID has developed the Performance Indicator Reference Sheet (PIRS) for GFSS,[72] which outlines a framework for tracking the progression of new or significantly improved technologies, practices and approaches from R&D to demonstrated uptake by stakeholders. The PIRS framework, specifically Phase III outputs (see below), provides a foundation to discuss IL outputs; however, IL stakeholders have reported that this framework may not be accurate in reporting some of the technologies that have already been scaled.

The PIRS framework disaggregates outputs from ILs into three R&D categories (Plant and Animal Improvement research, Production Systems Research, and Social Science Research), then into the four phases of research (Phase I - Under research as a result of U.S. government assistance, Phase II - Under field testing as a result of U.S. government assistance, Phase III - Made available for uptake as a result of U.S. government assistance, and Phase IV- Demonstrated uptake by the public and/or private sector). The four phases of research are described in Table 2 below.

[72] "Feed the Future Indicator Handbook," Feed the Future: The U.S. Government's Global Hunger & Food Security Initiative, November 2023.

The progression of technologies, practices and approaches across the four phases of research can be illustrated in context of the development of an improved seed variety. In Phase I, a breeding program may work to develop a new drought tolerant seed variety, which is tested under controlled conditions, such as in a laboratory or greenhouse. Upon successful results, the development of the improved variety would move to Phase II, where the variety undergoes field testing to evaluate its performance under real-world conditions. Once the field testing confirms its effectiveness for its intended end user, Phase III involves securing necessary approvals (e.g., variety registration or certification), enabling intermediaries like seed companies to legally multiply and disseminate and use the improved variety. Finally, in Phase IV, the new variety has a track record of being widely disseminated through various channels, without U.S. government assistance.

Table 2: Performance Indicator Reference Sheet (PIRS) for GFSS

Phase	Status	Criteria for Classification
Phase I	Under Research	Technologies and management practices are considered to be under research when developed or tested in controlled conditions, such as laboratories, greenhouses, or confined settings for livestock. For social science research, only studies on specific approaches with the potential to significantly improve development outcomes are included.
Phase II	Under Field Testing	Research on a promising technology or practice is tested under conditions similar to those of potential users to assess effectiveness. This testing can occur in actual user facilities or replicated environments. The aim is to gather real-world performance data and ensure compliance with legal requirements. Social science research at this stage involves randomized controlled trials or quasi-experimental pilots to determine effectiveness.
Phase III	Made Available for Uptake	Technologies, practices, or approaches are considered ready for real-world utilization and can be disseminated to end-users by public or private entities, ensuring sustainable, widespread use. This phase requires meeting conditions such as licensure or certification and passing regulatory approvals, allowing legal use and dissemination by intermediaries and end-users. Social science research in this phase involves findings on an approach or innovation that has been available for uptake by development programs and the public or private sector, including policy guidelines, formal training with training materials or evidence-based toolkits.
Phase IV	Demonstrated Uptake by the Public and/or Private Sector	A public or private sector entity institutionalizes or supports dissemination of technologies, practices or approaches, independently of U.S. government assistance. This phase does not include utilization by donor organizations or end-users such as individual customers or farmers. In this phase, demonstrated uptake of social science research means support for or adoption by public and/or private sectors including institutionalization into a host country government's national policies or legal frameworks or delivery via public or private extension agents.

However, as shared during stakeholder consultations with ILCI and as discussed in the Feed the Future Indicator Handbook, some agricultural IAs may not pass through all phases or reach Phases III or VI of research given the nature of their product and their intended end user. In cases where technologies are co-developed with and for use by IL research partners, even if the technology does not reach farmers, it has already successfully reached its intended end-user.

The distinction of outputs across the three research themes (E.G.3.2-7) and four phases of technology are useful frameworks for MEL. The use of these frameworks not only aids in gathering useful data for tracking progress and categorizing innovations but also ensures that technologies are being developed and tested with end-users in mind. During stakeholder consultations with ILs, a number of interviewees noted that, although much effort is invested in advancing technologies through Phases I and II, significant gaps remain in Phases III and IV, where less attention is given to dissemination of outputs developed by the ILs. This may be partly because the majority of the budget and resources from USAID as well as the skills of ILs are more focused on Phase I and II.

Though the abovementioned framework is helpful in demonstrating uptake IL outputs, there is no process to identify these IAs from an IP management perspective. In fact, ILs have reported that they do not have a coherent approach to IP management and mainly defer to IL partners, which apply their own institutional IP policies barring certain exceptions. However, these policies are tailored to their own institutional goals and may not have the capacity to scale technologies developed by the ILs at the desired rate. The legal and policy framework discussed above (in Section 2) is meant to enable ILs to scale technologies; however, the gaps in these policies, especially those relating to agricultural IAs, leave room for USAID to guide ILs (and other grantees) on better management of IP.

3.2. Types of Technologies, Practices, and Approaches Developed by Innovation Labs

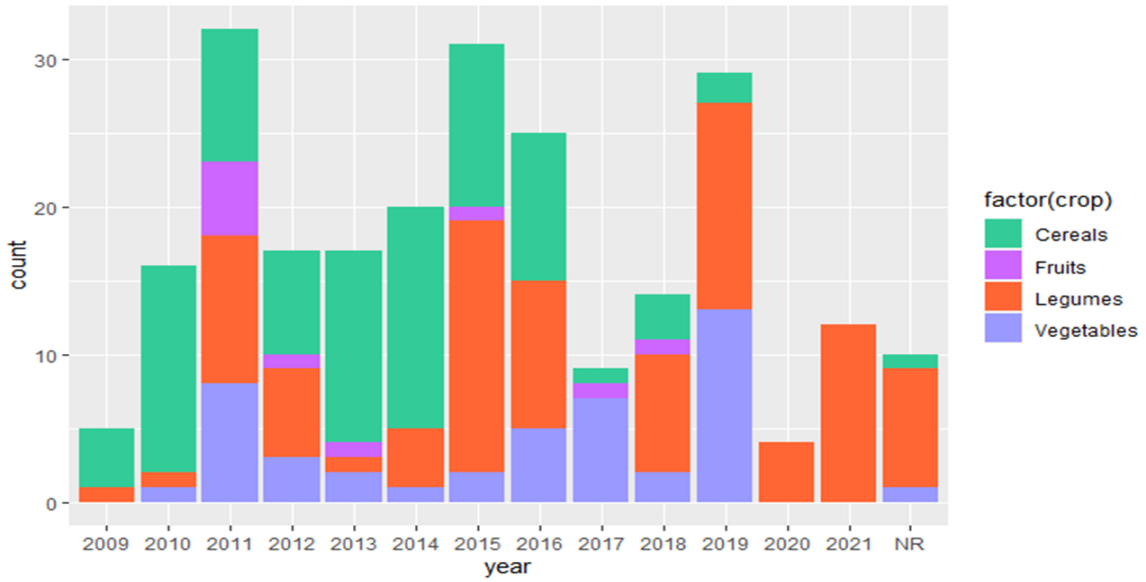
Implicit in the Theory of Change behind the ILs is the assumption that technologies, practices and approaches developed through the research ecosystem will be deployed at scale to solve specific challenges in agri-food systems. ILs have developed a range of IAs in furtherance of these goals. For the purposes of this report, the key outputs from ILs are classified within one of the following five categories: improved varieties, publications, digital assets, novel devices and processes, and animal vaccines. This classification is based on the physical attributes of the technologies rather than the three research themes described above, as the legal implications are more closely tied to these specific physical characteristics. These are briefly described below, followed by additional background on the type of IA or IP these innovations constitute. Table 3 below harmonizes PIRS output guidelines with the five types of IAs followed by a discussion on each type of IA.

Table 3: Key IL Outputs and IAs across the USAID Three Research Themes

Research Category	Phase III Outputs (with examples)	Intellectual Assets (IA) to be Managed
Plant and Animal Improvement	Each variety, improved line, or breed made available for dissemination is counted as a separate technology. To be considered Phase III, the technology must have passed all approvals (e.g., variety registration, certification, and biosafety approvals) such that intermediaries and end-users (e.g., service/input providers and farmers) are able to disseminate or use them legally.	• Improved varieties, cultivars, lines, and breeds • Publications • Digital Assets • Novel Devices and Processes • Animal Vaccines
Production Systems Research Production	New/improved system component or formal recommendations ready for dissemination to farmers, including guidance for where the practice is appropriate and other conditions for use. To be considered Phase III, the new/improved system component must have passed all required regulatory approvals such that end-users (e.g., service/input providers and farmers) are able to use them legally.	• Publications • Digital Assets • Novel Devices and Processes
Social Science Research	Social science research finding on an approach or innovation available for uptake by development programs and the public and private sector. Examples include policy guidelines or recommendations, a formal training with training materials, or evidence-based toolkits.	• Publications • Digital Assets

A key output from the ILs focused on plant and animal improvement is genetic gain in edible plants and animals. **Improved varieties** confer benefits to farmers, including enhanced productivity, improved nutrition, pest and disease resistance, improved shelf life, and climate change adaptability. As living organisms, research on plant and livestock varieties is highly regulated and often follows specified protocols, such as national performance trials to show value for cultivation and use (VCU) and distinctness, uniformity, and stability (DUS) before varieties are registered prior to commercialization, as required by several countries. Moreover, the movement of improved varieties across national boundaries is often governed by sanitary and phytosanitary measures to protect local consumers, animals, and plants from pests and diseases. Based on a database provided by USAID, as of 2022, more than 280 registered crop varieties have come out of ILs. Figure 2 below shows the distribution of new varieties from ILs across time and crop type.

Figure 2. Distribution of New Varieties from ILs Across Time and Crop Type



*For ILs focused on social science and public policy research, **publications** are often their main outputs. Given that all ILs are housed within top U.S. universities working in collaboration with other research centers, they all produce publications in the form of peer-reviewed journal articles, books, manuals, toolkits, training materials, policy briefs, reports and other grey literature. To date, over 1,000 publications have been produced by ILs and their research partners. These publications capture findings that can be used to better understand emerging challenges and share lessons on good practices. Among the main audience for research publications are other researchers who in turn build the stock of scientific knowledge, policymakers who use them to guide reforms, and donors which rely on publications to better target investment priorities.*

Digital assets are a relatively new but fast-growing output from ILs. Digital assets include specialized software and code, unique databases and datasets, multimedia files, and mobile applications (which combine software, data, and design elements). A good example of such a digital asset is the PlantVillage dataset, developed by the IL for Current and Emerging Threats to Crops at Pennsylvania State University in partnership with the United Nations Food and Agricultural Organization (FAO), CGIAR Centers, and NARES.[73] This proprietary software collects and analyzes data on crops, pests, diseases, and environmental conditions from farms worldwide, which is used in developing predictive models and tailored solutions for farmers to improve their yields and manage risks. With the growing use of Artificial Intelligence (AI), such datasets are becoming increasingly valuable. At the same time growing concerns over data ownership, privacy, storage, and sharing are further complicating the management of such assets, all of which have significant legal and contractual implications.

ILs can also generate novel products and processes that solve unique challenges within agri-food systems. Several outputs from the production systems research ILs fit in this category. A classic example is the Purdue Improved Crop Storage (PICS) bags, a type of hermetic storage technology developed to help smallholder farmers store their grains and other crops without the use of

[73] "About," Plant Village, accessed August 23, 2024.

chemicals.[74] These bags are designed to protect stored crops from pests, moisture, and mold, significantly reducing post-harvest losses. Another example is the multi-crop thresher[75] a labor-saving mechanical device designed by Soybean Innovation Lab and partners to "relieve the huge burden of stick threshing that is often done by women and young people" in many African countries. SIL collaborated with three Ghanaian Universities to crowdsource the design of the low-cost thresher through a student competition and is now providing training programs for young engineers, equipment fabricators, and vocational schools to enable the local manufacture of this and other agricultural equipment.

For livestock and fisheries, **vaccines** offer a cost-effective and environmentally sustainable way of reducing animal mortality due to pests and diseases. Currently, two ILs are developing vaccines. The Feed the Future IL for Fish is developing a vaccine that will reduce aquaculture losses due to fish mortality from identified disease-causing agents, thereby reducing antibiotic use and preventing antimicrobial resistance.[76] Similarly, the Feed the Future IL for Animal Health at Washington State University, in collaboration with the International Livestock Research Institute (ILRI), the Kenya Agricultural and Livestock Research Organization (KALRO), and the University of Nairobi, is developing vaccines and diagnostic tests for East Coast Fever, a tick-borne disease common in East Africa that is fatal to cattle and humans.

The above typology of outputs from the IL is neither exhaustive nor mutually exclusive. For example, the development of a new crop variety often generates multiple publications and datasets that have independent value as intellectual assets or research outputs. However, as shown below, this typology provides a useful framework for analyzing the protection of IAs from the ILs. Further, legal protection of these IAs is based on the type of outputs. For example, for a new product or process, a patent application could be filed by the university based on university policies, USAID guidance, and federal law. Publications can be copyrighted. Improved varieties can be protected as a plant patent or under PVP laws in the United States (this varies by jurisdiction). These are discussed in detail in context of IL outputs below.

3.3. Legal Protection of Intellectual Assets Developed by Innovations Labs

Depending upon the policies of the university and goals of the IL, some IL technology could be legally protected as IPR in the form of trademarks (e.g., brand name), copyrights (e.g., knowledge products), patents (e.g., vaccines), or another form of IP. This will depend upon the nature of the product and priorities of the IL and university. In the United States, new plant varieties could be protected as plant patents or PBR/PVP, while some jurisdictions do not allow for patenting of living

[74] D. Baributsa et al., "PICS Bags Safely Store Unshelled and Shelled Groundnuts in Niger," *Journal of Stored Products Research* 72 (2017):54-58.

[75] Amy Karagiannakis, "Soybean Innovation Lab is Mechanizing Agriculture Across Africa with Multi-Crop Thresher," *Agrilinks,* Feed the Future, February 26, 2021.

[76] Mazuba Siamujompa et al., "An Investigation of Bacterial Pathogens Associated with Diseased Nile Tilapia in Small-Scale Cage Culture Farms On Lake Kariba, Siavonga, Zambia." *Fishes* 8, no. 9 (2023): 452.

matter.[77] This section sets out the different forms of IPR, including details of what is protected, time period of protection and registration, followed by guidance provided under ADS 318 on the right of contractors pursuing protection for technology developed under USG contracts.

Patents are legal rights over a new invention, which allow the owner to prohibit development, use, distribution, importation, or sale of the patented invention without their consent.[78] Once a patent is awarded, the patent owner has the exclusive right for a limited period of time (usually 20 years) to exploit the invention but only within the jurisdiction of country or region where the patent has been approved. Patents are jurisdictional, although there is an international patent system under the World Intellectual Property Organization (WIPO) Patent Cooperation Treaty, which has 157 contracting states. Generally, in order to be patentable under U.S. law, an invention must be (1) new and useful (35 USC §101), (2) novel (35 USC §102), (3) non-obvious (35 USC §103), and (4) able to be described adequately (35 USC §112).[79] U.S. law (35 U.S.C. § 161 *et seq*.) specifically addresses "plant patents" which confers right to "exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States." A few other countries worldwide extend patent protection to plants, but many apply sui generis IP protection for plants instead, in line with Article 27.3 of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). In the United States, plant varieties may be protected as either patents or under the U.S. law on plant variety protection, as explained below. As per upstream policies (federal law, USAID, and university policies) for management of IA/IP, the university has the right to pursue patent protection for federally funded technology, and the USG has a use right to the technology (subject to rights and restrictions discussed in section 1).

Copyrights are IP rights over literary and artistic creations which can include books, music, painting, sculptures, films and technology-based work.[80] A copyright gives the author the right against those who "copy" or exploit their original work without their consent. A copyright need not be formally registered, unlike a patent, and it has protection as soon as it exists and need not undergo a formal registration process. As per ADS 318, while government publications are not copyrighted in the United States, publications developed by contractors using government funding may be.[81] Contractors must proactively protect their technical data and computer software rights, particularly with pre-existing programs or those developed with other funding.[82] It is important to

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[77] TRIPS Article 27.3 states that "Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof." PBR is not included in the TRIPS agreement and would fall under the UPOV Convention or other national laws. *See* Savita Mullapudi Narasimhan et al., "Towards a Balanced 'Sui Generis' Plant Variety Regime: Guidelines to Establish a National PVP Law and an Understanding of TRIPS-plus Aspects of Plant Rights," UNDP, 2008.

[78] "Patents," World Intellectual Property Organization (WIPO), accessed May 10, 2024.

[79] *See* "Manual of Patent Examining Procedure," USPTO, Section 2103.

[80] "Understanding Copyright and Related Rights," WIPO, 2016.

[81] See e.g., ADS 318.3.2.

[82] *See* FAR 52.227-14 alts. I, II & III; ADS 318.3.2.1 and 318.3.2.2; *see also* Susan B. Cassidy, "What Every Company Should Know about IP Rights When Selling to the US Government," *Landslide* 9, no. 6, July/August 2017.

understand data rights for contractors developing software or technical databases because the government has different licensing rights depending on when and with what funding that technology was developed. The government may have an unlimited or limited right to a contractor's technical data. Data rights are usually governed by FAR 52.227-14, which provides that the government has an unlimited right to technical data and software and can disclose and use this data "for any purpose."

Trademarks are IP rights that distinguish goods and services of one entity from others using a mark or identifier. U.S. trademark law is governed by the Lanham Act. (15 U.S.C. §§ 1051 et seq.). Whether registered or unregistered, trademarks must be (1) distinctive, (2) nonfunctional (as opposed to something patentable), and (3) used for commerce.[83] However, if a trademark becomes generic with overuse (such as aspirin, zipper, etc.), the trademark protection disappears. Some of the ILs have protected their trademarks. Trademarks are also jurisdictional, but an international trademark could also be filed under the Madrid Protocol for International Trademark Registration, which gives registrants the advantage of a streamlined application process and the payment of one set of fees, which can significantly reduce administration costs.[84] In order to file an international trademark, an individual or entity must be connected to one of the Madrid Protocol's 114 members.[85] When filing under the Madrid Protocol, any existing trademark registrations in participating countries will automatically be replaced with an international trademark, but will retain the earlier filing date of the national trademark.[86] Although ADS 318, does touch upon trademarks, in which USAID has the right to protect its own interest under USG projects, issues such as trademark licensing are not addressed.

Plant Breeder Rights confer rights that allow a breeder to claim ownership over developed varieties. To claim PBR, the breeder must establish novelty of the plant variety and confirm distinctness, uniformity, and stability (DUS). In the United States, plant varieties may be protected under the Plant Variety Protection Act of 1970 if it is (1) new (not sold in the U.S. market for more than one year before filing or outside of the U.S. market for more than four years), (2) distinct, (3) uniform ("describable, predictable, and commercially acceptable"), and (4) stable.[87] PBR/PVP covers rights in relation to breeding, registration, commercialization, and marketing of plant varieties for a period of time (typically 15-20 years). U.S. law confers the right to exclude others from selling, offering for sale, reproducing, importing, exporting or using to produce hybrid or different varieties. (7 U.S.C. § 2541.). Members of the International Union for the Protection of New Varieties of Plants (UPOV), which establishes a framework for PVP, require a breeder's permission before a plant variety is grown for commercial use.[88] Within Africa, the *Organisation Africaine de la Propriété*

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[83] "An Introduction to Trademark Law in the United States," Congressional Research Service, July 24, 2023.

[84] "Summary of the Madrid Agreement Concerning the International Registration of Marks (1891) and the Protocol Relating to that Agreement (1989)," WIPO, accessed August 23, 2024.

[85] "Guide to the Madrid System: International Registration of Marks under the Madrid Protocol," *WIPO Publication No. 455E/22* 16, 44, 2022.

[86] "Guide to the Madrid System: International Registration of Marks under the Madrid Protocol," 17.

[87] 7 USC § 2402(a).

[88] "What is Plant Variety Protection?" UPOV, accessed August 23, 2024.

Intellectuelle (OAPI), a member of UPOV, allows plant varieties registered in one member's jurisdiction to apply to all member states whose national laws do not provide otherwise.[89] ADS 318 does not mention PBR or PVP protection.

Table 4 below sets out the types of formal IPR protection that can be sought for IAs developed by ILs.

Table 4: Forms of IPR Based on Type of IA

Type of IA	Types of Legal Protection			
	Patents	Plant Variety Protection	Copyrights	Trademarks
Improved Varieties	✓	(✓)		✓*
Research Publications			(✓)	✓*
Digital Assets	✓		✓	✓*
Novel Devices and Processes	✓			✓*
Animal Vaccines	✓			✓*

Notes: ✓= Forms of legal protection that could be applied based on type of IA; (✓) = Most common legal protection that is applied to IA; ✓ = Trademarks could be obtained based on brand name or symbol irrespective of type of IA.*

Improved varieties developed by ILs are owned by host universities and are most commonly protected under plant patents or PVP/PBR. This right is conferred under the BDA,[90] U.S. Law on Patents for Plants,[91] and the U.S. Plant Variety Protection Act.[92]

Novel devices and processes are protectable under patents, trademark, and copyrights and fit within the current legal structure governing USAID-funded research. Unlike many other countries, U.S. law requires relative novelty for patents, which means that an invention may be sold or publicly disclosed one year before the patent is registered and still be considered novel.[93] Current U.S. IP law provides for a one-year grace period from the filing date of a U.S. or foreign patent application.[94]

[89] *See* David Cochrane and Craig Kahn, "Five Facts to Note about PBR Status Quo in Africa," *CIOPORA*, January 22, 2021.

[90] The BDA states that plant varieties are eligible for protection.

[91] U.S. Law (35 U.S.C. § 161 *et seq*.) specifically addresses "plant patents," which confer the right to "exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States."

[92] The United States has a Plant Variety Protection Act, and U.S. law confers the right to exclude others from selling, offering for sale, reproducing, importing, exporting, or using to produce hybrid or different varieties (7 U.S.C. § 2541).

[93] 35 U.S.C. § 102(b); "2152 Detailed Discussion of AIA 35 U.S.C. 102(a) and (b) [R-11.2013]," U.S. Patent and Trademark Office, accessed May 10, 2024.

[93] 35 U.S.C. § 102(b); Jeffrey M. Kaden, "Patent Protection and the Novelty Requirement," Gottlieb, Rackman & Reisman, 2024.

[94] "2152 Detailed Discussion of AIA 35 U.S.C. 102(a) and (b) [R-11.2013]," U.S. Patent and Trademark Office, accessed May 10, 2024.

A large number of outputs from ILs are **publications** in the form of journal articles, periodic reports, technical reports, presentations, student outputs and other grey literature. Copyrights are generally claimed for these IAs, with certain minimum standards of protection based on international treaties such as the Berne Convention for the Protection of Literary and Artistic Works and the WIPO Copyright Treaty.[95] While authors generally retain copyright, the research and underlying data are encouraged to be made public for publicly-funded research publications. For IL publications, authors usually retain copyright ownership in scholarly work; however, in many cases universities require a royalty-free license for use within the university. For scholarly work that uses a substantial amount of university resources, such as specially funded projects or "work-for-hire," the university will retain ownership. USAID advises management entities to create a Data Management Plan that adheres to the USG's Open Data Policy, outlined in ADS 579, which provides that data from federally funded projects should be published in USAID's DDL. There are certain exceptions, however, and USAID only has limited rights to data that is "commercial or financial and confidential or privileged." For instance, it may not publish data without permission from the funding recipient.[96] In terms of accessibility, USAID also has a comprehensive strategy for dissemination of federally funded research data and publication. This was recently released under the USAID: Public Access Plan.[97]

Digital assets developed by ILs include software, unique databases, multimedia files, and AI. Based on their characteristics, these assets may be patentable, copyrightable, or eligible for trademarking. For example, a data collection of images may be protected under copyright if it meets a minimum threshold of originality in usage, selection, or arrangement.[98] This is generally a low bar. An individual image's copyright would belong to the original creator (whether of a photograph or picture), and a database copyright would only pertain to the database as a whole. Alternatively, a database may be protected under a patent if it consists of a computer system with a particular retrieval and organizational method.[99] Although U.S. law on IP rights in AI programs is still in the early stages of development, an AI system could qualify as patentable if it fulfilled the qualification of novelty and other requirements. An AI program, by its nature, requires large amounts of data to function, so it could be thought of as a huge database that also involves the creation of an algorithm (patentable software) to run. U.S. law covers some database copyright and patent issues, but there are considerable open questions regarding data privacy and storage.

Vaccine related technology being developed by IL for Fish and IL for Animal Health (in collaboration with ILRI, KALRO, and the University of Nairobi) could be eligible for patent protection. Inventions that can be patented in the field of veterinary medicine include a "new

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[95] *See* "International Issues," U.S. Copyright Office, accessed August 23, 2024.

[96] ADS 318.3.2.2(a)(2); ADS 579.3.3.3.

[97] "USAID Public Access Plan: Ensuring Free, Immediate and Equitable Access to Results of Federally Funded Scientific Research USAID, " USAID, March 28, 2024.

[98] Daniel Glazer, Henry Lebowitz, and Jason Greenberg, *Data as IP*, Reuters (May 2024), https://www.reuters.com/practical-law-the-journal/transactional/data-ip-2024-05-01/; *Feist Publications, Inc. v. Rural Telephone Service Co*., 499 U.S. 340, 354-60 (1991); *CCC Info. Servs., Inc. v. Maclean Hunter Mkt. Reports*, *Inc*., 44 F.3d 61, 65 (2d Cir. 1994).

[99] Daniel Glazer, Henry Lebowitz, and Jason Greenberg, "Data as IP," *Reuters*, May 2024.

vaccine" or a "new use of an old active ingredient," such as a "new route of administration."[100] The patentability of a subject matter is determined by its utility, novelty, non-obviousness, and the "sufficiency of the disclosure in the patent specification as filed."[101] The test of sufficiency asks whether a specification gives enough information for a skilled reader to "make and use the claimed invention without 'undue experimentation.' In the context of veterinary medicine, the number of "working examples, especially in multiple species" included in the specification can be an important element in determining patentability.[102] In the United States, USDA regulates veterinary vaccines, which fall under the category of veterinary biologics (VB).[103] The controlling act here is the 1913 Virus-Serum-Toxin (VST) Act, which authorizes USDA to "ensure that all veterinary biologics produced in, or imported into, the United States are not worthless, contaminated, dangerous, or harmful."[104] The Agricultural Research Service, an in-house research agency of USDA, "pursues patent protection when it facilitates technology transfer."[105] USDA notes that vaccine patents can facilitate technology transfer by creating an "incentive for investments by private sector" that is hesitant to take up the expensive process of acquiring regulatory approval without the "promise of market exclusivity to justify investment."[106] It also adds that patenting vaccines can "expand[]" their "use to foreign countries."[107] Under the current patent regime, "it is not possible to obtain patent protection with global, world-wide effect."[108] However, the PCT enables an applicant to "submit a single application that becomes eligible to go forward as an application" in the Contracting States.[109] Such an application "has the same effect as a national application filed in each Contracting State of the PCT," and the application "may be filed by anyone who is a national or resident of a PCT Contracting State."[110] Each application is subjected to the respective national and regional law of the jurisdiction in which it is filed.[111] Notably, USDA has its own patent policy concerning veterinary vaccines, highlighting policy specificity that may be helpful in the context of USAID.

Currently there are no upstream policies or procedures in place to capture the possibility of obtaining IP for IL outputs. IL stakeholders mentioned that if a technology is developed exclusively in a lab, the university owns it and will go ahead with its commercialization. However, agricultural technology developed with USAID funding is collaborative and exists mostly outside the purview

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[100] James M. Gould, "An Overview of Patent Law as Applied to the Field of Veterinary Medicine," AAPS Journal 10, no. 1,(March 2008):1-8.

[101] *Id.*, at 2.

[102] *Id.*

[103] "Veterinary Biologics," USDA, last modified August 20, 2024.

[104] "Common Questions About Veterinary Biologics," USDA, last modified March 18, 2024.

[105] "Technology Transfer: Animal Vaccines," Office of Technology Transfer, Agricultural Research Office, USDA, 2019.

[106] *Id.*

[107] *Id.*

[108] "Patent Landscape Report on Animal Genetic Resources," *WIPO* 35, 2014.

[109] *Id.*

[110] *Id.*

[111] *Id.*

of university policies that monitor, protect, and commercialize these technologies. Legal protection is often sought by IL partner institutions based on their own policies, which leaves a number of agricultural IAs outside scope of IA/IP management covered by BDA and ADS 318.

3.4. Dissemination and Scaling Pathways for Technologies Developed by Innovation Labs

Dissemination and scaling pathways are critical for ensuring that technologies from ILs reach intended end users. ILs do not have a uniform strategy or structure for scaling technologies, and dissemination is almost an afterthought for most ILs. The primary mandate of ILs is to do research, and scaling is not seen as part of their core function.[112] Further, there is no strategy for management of IA/IP, though some ILs, like the Innovation Lab for Crop Improvement (ILCI), stated that this will be a part of their project design in the future. Since ILs are based in U.S. universities, they rely heavily on local partners to disseminate and scale their technologies, and their approaches to manage the IA/IP developed are dependent upon the policies of other institutions.

USAID's GFSS 2017 technical guideline, the Research Output Dissemination Study (RODS),[113] and stakeholder consultations with IL directors and scientists all highlight that ILs largely use four delivery pathways for dissemination: commercial, public sector, public-private partnerships, and community-based partnerships. The choice of delivery pathway depends on the type of technology, market conditions, and institutional partners involved. Legal considerations also vary based on the dissemination or scaling pathways employed by the IL for each IA. Examination of these scaling pathways is critical to this study, as it highlights the current practices of ILs that constrain and enable dissemination and scaling of these technologies as well as legal implications.

While it is useful to separate dissemination and scaling into these four distinct pathways, it is important to emphasize that, in practice, these pathways are not mutually exclusive. For example, many technologies are first piloted with community groups, after which the public sector gets involved (e.g., raising awareness through extension services), which in turn bring the attention of the private sector once viable demand is established.

The sub-sections below examine the four common scaling pathways, focusing specifically on the relevant legal considerations surrounding them. These include the legal framework, comprised of top-down (from the U.S. government, USAID, and universities) and bottom-up (from IL partners) rules and policies for each pathway, along with the relevant legal instrument used to facilitate dissemination of the technologies for each pathway. Illustrative case studies, compiled from IL interviews and responses collected from a follow-up survey sent to selected ILs (Annex 3) are also included. These case studies further highlight some of the opportunities and challenges associated with each of these scaling pathways and relevant legal considerations.

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[112] "Research Output Dissemination Study: Examination of Dissemination Pathways in the Use, Adoption, and Scaling of Research Outputs of Feed the Future Innovation Labs," 5.

[113] *Id.*

Commercial Pathway

Commercial scaling pathways are typically used for technologies with high commercial value and market potential. In many cases, distribution through the private sector tends to be more sustainable, leading to greater longer-term impact beyond the term of donor funding. As stated in the *Scaling for Widespread Adoption of Improved Technologies and Practices Guidance Document*, "If scaling a particular innovation is profitable for private sector actors, it is likely to be sustainable and to eventually approach maximum potential scale."[114] An IL could, however, incur initial costs, depending on the interests of the private sector, including those associated with IP protection, such as filing and registration, maintenance fees, and administration costs associated with licensing and royalty collection,[115] which could make this pathway less appealing.

ILs generally do not pursue commercialization of their technologies for a number of reasons. First, some of the IAs may be produced due to their value as a public good and not just because they have high commercial value or market demand. Second, agricultural IAs like crop varieties are developed in partnership with partner institutions like CGIAR Centers and NARES that mostly focus on local adaptation and widespread use and impact. Third, many of the efforts of ILs are focused on getting technologies into Phases I and II and may require additional funding, time, or skills to commercialize these technologies. For instance, where the ILs choose a commercial partner to disseminate a technology and maximize use among end users, in many such cases, ILs first need to stimulate demand for their technology in the market in order to attract private interest for commercialization.

In cases where there is little effective demand from the end users or low financial returns, private sector actors may not have sufficient incentive to participate in the market. As profit maximizers, private companies are generally not interested in distributing technologies unless they are guaranteed financial returns. Moreover, the market risk that comes with new products often deters investments unless and until the right market conditions are met. Additionally, private sector companies often seek exclusive rights to technologies, inherently limiting accessibility, which can especially be a problem when the product is a public good and the private partner has limited ability to reach the entire focus market. To strike a balance between the public and private sector interests to maximize use and profit respectively, limited/semi exclusive licenses that are restricted by factors such as geography, number of licensees, or duration could be considered. "Use or lose" clauses could also be considered in licensing agreements, as some companies may seek licenses without an interest in commercializing products due to limited capacity, strategic objectives (i.e., remove a competing product from the market, which can be an issue with exclusive licensees), or speculative reasons.

The enabling environment around commercialization of IL technologies is multifaceted. The most relevant instrument here is the BDA, which was introduced to encourage commercialization of public research by permitting universities to pursue ownership of an invention. From consultations

[114] "Scaling for Widespread Adoption of Improved Technologies and Practices," Feed the Future, February 2023. .

[115] Stakeholder consultations conducted under the project (notes on file with the authors).

with stakeholders, it is clear that ILs themselves do not have strategies for management of IA/IP with high commercial potential and largely rely on either the university or institutional policies of IL partners to guide management of IAs/IP. As noted in Section 2, universities decide to commercialize technology on a case-by-case basis, and their policies generally address only commercial pathways. However, most of the ILs engage with their international partners, such as CGIAR Centers and NARES, in collaborative efforts to produce and disseminate new varieties, and in such cases, ILs have noted that they largely defer to partners to guide commercialization.

CGIAR Centers are guided by the CGIAR Principles on the Management of Intellectual Assets (CGIAR IA Principles),[116] their implementation guidelines,[117] and institutional policies that prioritize global public access of CGIAR IAs while striving to create a balance with the private sector (see Section 4). For instance, with respect to commodities like hybrid maize, where there is a high commercial interest, the International Maize and Wheat Improvement Center (CIMMYT) noted that it increasingly relies on the private sector (more than NARES) to disseminate varieties through semi-exclusive licensing agreements limited in geography and duration. This could be noted as a good practice for agricultural technology, as it does not limit the engagement of public sector actors such as NARES in accessing the varieties. In the case of OPVs, CIMMYT uses non-exclusive licenses. The NARES that pursue licensing with the private sector for commercialization and dissemination also rely most heavily on semi-exclusive and non-exclusive licenses, with some NARES intentionally shifting away from exclusive licenses due to their limiting nature. Most of these licenses transfer a use right and are not based on underlying IP, as most NARES do not protect their developed varieties under IP, with some notable exceptions such as some of the ARC varieties (KALRO is also planning to pursue IP protection for tea varieties). In order to help manage IAs/IP and licensing, some NARES have developed institutional IP policies that set out strategies for IP management and commercialization, amongst other things.

In some cases, ILs have developed technologies that have commercialization potential; however, stakeholders have flagged that they face challenges in generating market interest and could benefit from additional support from universities and USAID. This is illustrated in the PICS bag case study in Box 3. Here there was also an issue with enforcement of trademarks against knock-off products. Other ILs have expressed the need for greater commercial support and capacity. A stakeholder from the IL for Fish noted that some innovations they develop are too cumbersome to patent and have high implementation costs and challenges with market buy-in. Other ILs reported a lack of understanding of the necessary regulations or capacity to protect innovations. This illustrates a gap in the commercialization support provided by the host university and overarching considerations across ILs. Universities and USAID could support the development of step-by-step guides on these issues and promote ongoing knowledge development for ILs.

While USAID does provide some guidance on commercialization of IP developed under USG programs, this is limited by the considerations discussed above. The BDA encourages

[116] "CGIAR Principles on the Management of Intellectual Assets," CGIAR, Mar. 7, 2012.

[117] "Implementation Guidelines for the CGIAR Principles on the Management of Intellectual Assets," CGIAR, 2013.

commercialization through patents, and ADS 318 deals with IP rights and the USIAD use right. Funding recipients do use licenses with other partners, such as licenses of patents and copyright, including for software and data in the case of the latter. While it does not specifically cover licensing to third parties, USAID policy mentions allowable royalty conditions for patents.[118] It also covers situations in which the USG may register trademarks in the United States and other countries in order to protect its interests.[119] Overall, a more nuanced approach to management of agricultural technology with high commercial value is warranted in these instances.

Commercialization of agricultural IAs is also done through licensing agreements with third parties, which may provide exclusive rights within a defined geographic market (this is a semi-exclusive license due to the geographic qualification). The PICS program has made use of both semi-exclusive licenses and non-exclusive licenses, with regional licensing awarded based on the reach of a distributor. Semi-exclusive licenses have been limited in duration to five years, with the possibility of renewal. A licensing agreement for PICS bags also typically includes a target clause, which provides that the agreement can be terminated if certain targets are not met.[120] Other institutions use non-exclusive licenses, as an interview with one partner revealed is the case for open pollinated seed varieties. Regardless of the type of license, it can be a challenge to monitor and collect royalties, especially from licenses issued in different countries.[121] Another partner noted that that in addition to issuing non-exclusive and exclusive licenses, they use semi-exclusive licenses whereby a limited number of private companies are able to commercialize a particular plant or seed variety.[122]

Out of the ILs interviewed, only a few were successful in commercializing their technologies directly through the private sector. For improved varieties, for example, most are developed in partnership with public sector actors such as CGIAR Centers and NARES, which commercialize varieties through licenses (primarily use licenses) with private seed companies. Most of SIL's varieties, for example, are developed in partnership with IITA and NARES, in which case, their institutional policies on dissemination and commercialization of the variety apply.

Commercialization of crop varieties through the private sector is the dissemination pathway of choice for ILs that are producing high value crops such as soybean, hybrid maize, and horticulture. Box 1 provides an illustrative case study of elite soybean varieties, developed by the Soybean Innovation Lab and IITA, which are being licensed to private seed companies across Africa.

[118] ADS 318.3.1.6.

[119] ADS 318.3.3.1.

[120] Stakeholder consultations conducted under the project (notes on file with the authors).

[121] Stakeholder consultations conducted under the project (notes on file with the authors).

[122] Stakeholder consultations conducted under the project (notes on file with the authors).

Box 1: Case Study on Soybean Innovation Lab and IITA Licensing to Private Seed Companies

The **Soybean Innovation Lab (SIL)** at the University of Illinois was established in 2013 and works across 26 different countries in Africa, Asia, Latin America, and Australia, with active partnerships with 93 companies, organizations, research institutes, and universities to encourage soybean development.[123]

Technology: Soybean varieties come in both hybrid and OPV. For OPVs, the quality of saved seeds can decline over multiple generations. Factors such as genetic drift, disease, and pests can impact seed viability and vigor. Ideally, seeds should be saved for no more than 3 to 4 cycles to maintain quality. Soybean is typically grown by medium and large-scale commercial farmers.[124] While SIL has produced a variety of outputs and innovations, this case study focuses on the development of soybean varieties. In this case study, the varieties had not been protected under patents or PVP. However, the unique nature of soybean R&D emphasizes the importance of commercial scaling and dissemination pathways, particularly in order to secure involvement of private sector in scaling, offering an interesting case for IA management considerations.

SIL works with its international partners such as IITA and NARES to build breeding programs that allow local breeders to develop and deliver soybean varieties that farmers desire. Ideally, IITA would transfer the germplasm to the NARES through MTAs at no cost, which they could then develop and disseminate without additional agreements. However, the rate of soybean varietal release was very low in this case, resulting in only .08 varieties/country per year since 2000.[125] To expand dissemination, SIL worked closely with its partners, especially IITA, to build the capacity of its public sector breeding program and to consider revenue models that provide a more sustainable approach to promote development in the soybean sector.

Private Sector Engagement: In 2015, SIL launched the Pan-African Trials (PAT),[126] a unique market-led network of seed practitioners running formal trial programs, to create a catalogue of different seed varieties. This infrastructure established an entry point for regional varietal release and helped to generate interest from private sector companies to license IITA varieties. A licensing management system was used to ensure proper tracking of data and information.

SIL's PAT platform and strong private sector involvement has found success in disseminating and scaling soybean varieties. Since 2019, 27 new varieties have been released in seven countries, and the pipeline of new soybean varieties released increased from .08 to .96 per country per year.126F126F[127] Additionally, 17 new soybean varieties have already been successfully introduced to markets, with seven registered in Ghana, Ethiopia, Malawi, Mali, and Uganda and ten more in the

[123] "Activities and Impact Report 2020," Soybean Innovation Lab, 2020.

[124] "Soybean," IITA, accessed August 23, 2024.

[125] "IL Survey Response," Soybean Innovation Lab, 2024.

[126] J. Francischini and Z. Serelis,"Pan-African Trials Seed Catalog," Soybean Innovation Lab.

[127] "Variety Release Pipeline is Really Flowing," Soybean Innovation Lab, SIL Weely Newsletter, July 11, 2024.

registration process.[128] The success can be illustrated through the example of the first publicly bred soybean variety TGx-16FM.[129]

This improved variety was developed by IITA, through their collaboration with SIL, and disseminated through formal licensing agreements to eight different private seed companies across multiple countries.[130] These seed companies are required to pay a royalty and received three years of exclusivity. This variety is now available in multiple countries, such as Zambia and Zimbabwe, where it has been registered and approved for release and commercialization. IITA's research partnership with SIL also introduced revenue models that reduced reliance on donor funding and encouraged private sector engagement. This was achieved through licensing options to provide use rights to material, generate revenue, and hire key staff such as a lawyer and a product manager.

The shift from a more traditional seed system to one that involves licensing and royalties has also been particularly challenging for relationships between CGIAR Centers and NARES. NARES play a critical role in seed systems at the national level and should be provided access to technologies developed by ILs and CGIAR Centers. IITA experienced some push back as they moved towards licensing directly with the private sector, since the NARES have depended on revenue from licensing royalties to continue their research.[131] While this case study highlights that engagement with the private sector can be key to dissemination of some innovations (here improved varieties with commercial interest), it also underscores the interconnected nature of partners and institutions in seed systems. In particular, NARES continues to have an important role even when innovations can be commercially scaled, so their involvement should remain a consideration for publicly funded IAs.

Public Pathways

Technologies from ILs are often disseminated through public sector channels, as they are often purely public goods intended for broad accessibility. Local governments and other public sector actors often use government subsidies or extension services to help create awareness or demand, which can be especially important for the adoption of new products or practices. According to a 2012 study by Jayne and Rashid,[132] ten African countries spend over a billion dollars annually on agriculture subsidy programs, amounting to an estimated 29% of their public expenditure on agriculture.

The public sector in most middle to low-income countries targeted by ILs is often under-resourced, and shifting national priorities can make it challenging to consistently deliver technologies to end users. As is the case everywhere, public dissemination pathways that require government agency

[128]. "Activities and Impact Report 2020," Soybean Innovation Lab, 2020.

[129] "Pan-African Trials Seed Catalog."

[130] Stakeholder consultations conducted under the project (notes on file with the authors).

[131] Stakeholder consultations conducted under the project (notes on file with the authors).

[132] T.S. Jayne, and S. Rashid, "Input subsidy programs in sub-Saharan Africa: a synthesis of recent evidence," *Agricultural Economics* 44, no. 6 (2013): 547-562.

involvement are often subject to bureaucratic red tape, regulatory hurdles, and limited capacity.[133] Moreover, there is a risk of dependency if end users become accustomed to not paying for products and services. However, this pathway has the benefit of being able to distribute technology to those who need it most.

Public sector pathways are commonly used in cases where there is little market incentive because of thin margins, high risk, and/or small market size. In some cases, the private sector does not want to commit to investing in commercialization of untested agricultural innovations.[134] Through government extension services, public sector actors are often well positioned to raise awareness of new technologies to drive demand and train end users on how to properly use the new technologies or practices being promoted. Within the ILs, many cases of public sector dissemination pathways involve innovations with low commercial value or ones that are intended for historically marginalized end users, such as women, youth, and smallholder farmers who may lack financial capital to purchase new products.[135] However, in most cases the public sector receives little to no financial returns for their dissemination efforts.[136] Inadequate funding or reliance on donor support can often discourage the public sector from continuing its dissemination efforts, as these initiatives become unsustainable once funding stops.

Although the BDA and university policies have a public interest objective, they are primarily focused on commercialization of technologies. The BDA may even generate some resistance to putting inventions in the public domain, because it might discourage the private sector from turning inventions into products.[137] Further, there is no guidance in the form of USAID policy on managing technologies developed with a public good objective. On the other hand, IL partners such as CGIAR Centers work with an objective to ensure that public IAs achieve maximum socio-economic impact, engaging NARES to broaden national distribution and bolster local resources. At the national level, NARES are important partners of the ILs in local adaptation and extension of technologies, and the ILs can help build the technical capacity of the NARES.

ILs typically prioritize working through the public sector to disseminate products like improved varieties with low commercial value such as open pollinated crops (e.g., cowpea, millet, and groundnuts), vegetatively propagated crops (e.g., cassava and sweet potatoes) or technologies meant for use by the public sector.[138] Box 2 provides an illustrative case study of a digital tool, the Breeding Analytics Hub and QRlabelR, created by ILCI in collaboration with public research partners. These tools were developed using open-source, non-proprietary software to optimize breeding efficiency and support breeders in making choices about traits suitable for local needs.

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[133] Stakeholder consultations conducted under the project (notes on file with the authors).

[134] Stakeholder consultations conducted under the project (notes on file with the authors).

[135] "Research Output Dissemination Study," 5.

[136] *Id.*

[137] David M. Kettner and William J. Decker, "Fundamentals of Technology Transfer and Intellectual Property Licensing," *National Association of College and University Attorneys* 7-8, November 10 – 12, 2004.

[138] "Research Output Dissemination Study," 5.

Box 2: Case Study on Public Sector Pathways for Dissemination

The **Innovation Lab for Crop Improvement (ILCI)** at Cornell University brings together scientists and stakeholders from around the world to advance plant breeding tools, technologies, and methods aimed at delivering staple crops that can increase yields, enhance nutrition, and build greater resistance to pests and diseases. ILCI works alongside NARES to form sustainable solutions that fit the unique needs of each community and reduce hunger on a local and global scale.[139]

Technology: Despite the global development of breeding data management and analytics software, adoption of these tools by public sector breeding programs remains low.[140] This results in limited access to historical breeding data and insufficient resources to build reliable long-term datasets. Additionally, timely data is crucial when breeders need to make rapid scientific decisions.[141] ILCI has been working closely with its research partners to address these challenges. This can be demonstrated through the development of digital tools such as the Breeding Analytics Hub and the QRlabelR[142], which addresses several critical gaps to help improve data collection and management, building long-term reliable data sets fundamental to informed breeding decisions. The Breeding Analytics Hub, a cloud-based platform where software tools, code, documentation, and data are available in one place, was designed to enable breeders to organize and analyze large datasets quickly and effectively allowing them to maximize their response to selection and the value of their varieties.[143] This tool can be used to also help plant breeders make choices about traits and varieties that are suitable and meet local needs. Similarly, the QRLabelR was developed as a free companion software package to enhance digital data collection by allowing for electronic data capture through creation of QR labels for field plots that can be read by both humans and computers, improving user experience. This leads to availability of more accurate and quick data for breeding decisions. [144] The QRLabelR software was developed to be compatible with other digital phenotyping tools and breeding management platforms, allowing for seamless data sharing from field to analysis.[145]

Partnership with CGIAR and NARES: ILCI's work with the CGIAR, NARES, and other research institutions to establish these platforms highlights how public partnerships and dissemination pathways can be used to disseminate technologies that are intended for public sector partners. The R package created for the QRLabelR for example, has been downloaded more than 1,200 times since

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[139] "Feed the Future Innovation Lab for Crop Improvement," Cornell University , accessed July 31, 2024.

[140] "Breeding Informatics," Feed the Future Innovation Lab for Crop Improvement, Cornell University, accessed July 31, 2024.

[141] B. Lenaerts, B.C. Collard, and M. Demont,"Improving global food security through accelerated plant breeding." *Plant Science 287*, (2019):1102-07.

[142] The QRLabelR was developed by Alex Kena, a senior lecturer in the Department of Crop and Soil Sciences at Kwame Nkrumah University of Science and Technology in Kumasi, Ghana and supported by the LICI team.

[143] "Breeding Informatics," Feed the Future Innovation Lab for Crop Improvement, Cornell University, accessed July 31, 2024.

[144] K. Gashler, "New plot-labeling program supports plant breeders in Global South," Feed the Future Innovation Lab for Crop Improvement, October 26, 2023.

[145] "Semi-annual Performance Report FY 2024," Feed the Future Innovation Lab for Crop Improvement, Cornell University, April 2024.

it was released.145F145F [146] The Breeding Analytics Hub was co-created between U.S.-based researchers and data scientists working closely with data scientists and coders at ILCI's international partner institutions. This collaboration is crucial and provides important information used to further refine the platform. For example, during a project wide meeting with the Institut Sénégalais de Recherches Agricoles (ISRA), the NARES in Senegal, the Cornell team discovered that unreliable connectivity was an issue for international teams, especially when processing large data sets.

Dissemination Strategy: The dissemination of these technologies to NARES and other partners is typically done through an informal process, with no formal process in place for IP protection. It is unclear whether this informality reflects a deliberate philosophy or position or the newness of the program and its focus on tools, technologies, and methods with little commercial value.146F146F[147]

ILCI has sought to ensure that technologies developed under the program are open-sourced and freely available to end users, predominately public research institutions. To this end, technologies developed to date, such as the Breeding Analytics Hub and QRLabelR, were created using software and digital tools that are open access and freely available on the market or made to be open-sourced.

The digitization of materials and data was identified as a fundamental task required for successful and effective use of these technologies. While ILCI has provided significant support to build the capacity of its partners, for example through training, lack of digitization or poor connectivity have posed some challenges for dissemination of the technologies. Transitioning from old methods for data collection and management such a shift from handwritten, hard paper copies to digital format requires a change in mindset and behavior which can take time and may be a barrier for uptake.147F147F[148]

The ILCI team also identified that some partners may not be ready to take on the latest innovations, which can create challenges when trying to triangulate USAID's priorities with leadership and national programs' needs along with balancing what ILCI is able to provide. At this stage, the program does not have any intention of acquiring IP or royalties, nor has it found a need for CGIAR and NARES partners to have mutual exclusivity. However, in the long term this may not be beneficial for establishing a stable business model or for preventing IP abuses.

Though still in its early stages, ILCI has successfully leveraged public partnerships to develop technology that is practical for its users and that is scalable within its international partnership networks. While further refinement is needed, key lessons learned have emerged. First, involving the public sector in developing and disseminating technologies for its own use fosters buy-in and results in the development of more practical tools. Second, if the technology is intended to be publicly available, consideration needs to be given from the beginning for using freely available, open-sourced software that allows for the platform to scale at low or no cost, facilitating easier transfer and

[146] *Id.*

[147] Stakeholder consultations conducted under the project (notes on file with the authors).

[148] T.W. Rife, C. Courtney, G. Bauchet, M. Neilsen, and J.A. Poland, "Intercross: An Android app for plant breeding and genetics cross management," *Crop Science* 62, no. 2 (2022):820-24.

adoption of the technology. Third, it is crucial not only to build the technology itself but also to build capacity of the end users through training, equipping them with the necessary skills and knowledge to effectively apply these technologies in their contexts.

Public-Private Partnerships

The primary idea behind Public-Private Partnerships (PPP) is to leverage the strengths of both the public and private sectors to achieve outcomes that might not be possible through individual efforts alone. For most technologies generated from ILs, PPPs may be the most effective dissemination and scaling pathway, as they balance the pros and cons of purely commercial and purely public pathways and engage partners across both the public and private sectors. This pathway also allows for both the public and private sectors to address issues of supply and demand constraints, together creating a more expansive system for reaching end users. Government instruments such as subsidy programs can be used under different scaling pathways, including PPPs, in order to encourage uptake of agricultural innovations.

Some key issues that arise from this pathway include differing priorities and roles of the public and private sectors as well as relevant policies and regulations. These factors can create some challenges in coordinating dissemination efforts. Under the PICS program, PICS bags are manufactured by the private sector and have been distributed to end users with government support to several countries across West Africa. In an interview with a stakeholder from the PICS program, while the product was initially given away for free, trademark protection and a commercialization pathway were later employed to protect against copycat products. Although this transition was difficult, the Purdue Research Foundation helped obtain a trademark, and BMGF provided funding to develop the supply chain and build capacity.[149] Box 3 highlights the PICS bags case study.

Box 3: Case Study on Public-Private Sector Pathways for Dissemination

Purdue Improved Crop Storage (PICS) bags have a long history and were developed in the late 1980s through a collaboration between Purdue University and West and Central African farmers with funding under USAID's Bean-Cowpea Collaborative Research Support Program (CRSP). They were first commercialized in 2007 with support from the Bill and Melinda Gates Foundation. This included pilot testing and partnerships with CGIAR Centers, NARES, NGOs, and the private sector across ten African countries. Subsequent Projects (PICS2 and PICS3) expanded the technology to other crops, refined dissemination strategies through public and private channels, and used ICT for enhanced farmer training and market integration.[150]

[149] Stakeholder consultations conducted under the project (notes on file with the authors).

[150] "Feed the Future Innovation Lab for Food Processing and Post Harvest Handling: Project Overview" Feed the Future, Purdue University, accessed August 23, 2024.

Technology: The PICS bag is a cost-effective, simple technology for low-resource farmers, designed to preserve dry crops for months post-harvest without insecticides. PICS bags use hermetic triple-layer plastic to prevent insect damage.[151] While different approaches have been used for dissemination and scaling of PICS bags, the project's evolving partnership with both the public and private sectors across different countries and regions provides an interesting case of successful scaling.

Since 2008, PICS bags have reached around 40 countries through public-private partnerships. Dissemination approaches varied, involving market-driven collaborations with local governments, extension services, CGIAR Centers, NARES, and NGOs to train farmers and generate demand.

Public Sector Engagement: Public extension services' demonstrations improved farmers' post-harvest management and awareness of PICS bags.[152] Public sector not only played an important role in creating publicity and demand for the PICS bags, but some governments also supported them through national programs that purchased and distributed bags or provide tax exemptions for raw materials. For example, the government of Niger purchased one million PICS bags that were distributed to food reserve facilities or stores across the country, which helped to build awareness among workers handling bags and storing grain.[153]

Private Sector Engagement: Private sector partnerships with plastic manufacturers, distributors, and vendors strengthened supply chains for last-mile delivery. Private sector involvement was initially challenging due to lack of product knowledge, limited capital, low demand by smallholder farmers, reluctance to engage due to risk associated with a new product, and inefficient distribution networks linked to contract enforcement issues.[154] To stimulate private sector production, funding for start-up costs for manufacturing and distribution was provided by the project to de-risk initial investments. However, this initial approach was not sustainable, as there were no agreements in place to promote accountability, and many private sector companies failed to pay back the start-up funding provided by Purdue to invest in production of the bags.

IP Protection and Commercialization: PICS bags are a relatively rare example of an IP-protected technology developed through the ILs that has been broadly disseminated. In this case, IP protection was not an initial priority, but, as demand for PICS bags rose, so did competition from counterfeit bags, prompting the project to pursue IP protection through trademarks. In 2010, Purdue established PICS Global,[155] a private social enterprise responsible for granting licenses to manufacturers and distributors and managing the PICS trademark globally. The PICS trademark was acquired by the Purdue Research Foundation (PRF), which also supported the establishment of PICS Global and provided consultation to the project on how to approach IP and help with registration around the

[151] IL Survey Response, 2024 (notes on file with the authors)..

[152] D. Baributsa and M. C. Concepcion Ignacio et al., "Developments in the use of hermetic bags for grain storage," *Burleigh Dodds Series in Agricultural Science* (2020): 171-98.

[153] IL Survey Response, 2024 (notes on file with the authors)..

[154] "5th International Working Conference on Stored-Product Protection," *International Journal of Tropical Insect Science* 10, no. 4 (1989): 63.

[155] "About PICS Global," Purdue Improved Crop Storage (PICS), PICS Global, accessed August 23, 2024.

world. Trademarks were pursued in multiple countries at once under the Madrid Protocol. PICS Global now pays royalties back to PRF, the original owner or the trademark. Manufacturers and distributors pay a small royalty fee (3-5% per bag) to PICS Global, funding trademark registration, promotion, and staff support.

PICS Global offers exclusive and non-exclusive licensing agreements. Exclusive licenses, typically for 2-5 years, set milestones, incentivize market development, and hold partners accountable. This flexibility allows adjustments and termination of agreements if suppliers fail to meet predefined production standards and targets. A dedicated entity such as PICS Global also allowed hiring of staff with business acumen to drive brand recognition while managing technology transfer.

Despite successes, limitations persist in commercializing PICS bags. Fake PICS bags, sold at lower prices but of lower quality, risk losing customer trust, especially in markets with minimal awareness of hermetic bags. Awareness campaigns and training helped to educate customers on identifying genuine PICS bags. Moreover, licensing agreements lacked provisions focused on maintaining product quality, which arose due to supply chain issues and false marketing of bags. Monitoring these globally is challenging, especially without set standards.155F155F[156] Differences in regulations and markets across countries complicate dissemination pathways and IP management. Some countries, particularly those outside of the Madrid Protocol system require additional national-level trademark registration, posing a burden on PICS Global and potentially disincentivizing private sector involvement in new markets.

Successful dissemination and scaling of PICS bags stemmed from long-term strategic relationships, incentives for protection of IA, and continuous learning, rather than the novelty of the innovation. PICS bags' global success was the result of over three decades of R&D, partnerships, and pathway development for effective dissemination, highlighting several key lessons. First, even with private sector involvement, government/public participation throughout the entire process from R&D to dissemination is crucial for creating awareness and driving demand. Second, successful technology transfer takes time and must be adapted differently in each country. Third, it might be necessary to set up a dedicated entity or specialized team like PICS Global that is responsible for dissemination and scaling.

Community / Civil Society Based Pathway

Working through community-based pathways often allows partners to address the immediate needs of local communities. Dissemination and scaling efforts that are done in close coordination with local actors who understand the context and have direct connections with end users can lead to greater uptake and adoption of different innovations. Additionally, community-based pathways can be useful when it comes to innovations that require a shift in behavior like introducing a new production practice that is not a physical technology being sold in the market. For example, in the case of disseminating knowledge on production practices a community-based organization can be

[156] "Developments in the Use of Hermetic Bags for Grain Storage."

a good fit when it is necessary to work closely with farmers throughout the research and dissemination process.[157]

A significant challenge associated with this dissemination pathway is that many of these organizations are heavily dependent on donor funding, which can present challenges for long-term sustainability. Moreover, quality control and standards are difficult to maintain given the informal arrangements and limited technical skills in most community-based organizations.

Community-based pathways are typically used by ILs that promote new practices and processes like promotion of conservation agriculture or improved varieties for orphan crops like groundnuts that are not profitable for seed companies.[158] An illustrative case study of new peanut varieties developed by the Innovation Lab for Peanut (Box 4) shows that these improved varieties are being multiplied and distributed through grassroots initiatives supported by farmer groups and NGOs.

Box 4: Case Study on Community Based Pathways for Dissemination

The **Feed the Future Innovation Lab for Peanut** or Peanut Innovation Lab at the University of Georgia operates in countries where peanuts are an important source of food security, cash revenue, and agricultural diversity. Its research applies innovative science to improve peanut production and use, raise awareness on nutrition, and increase food safety in developing countries. In addition to developing new peanut varieties, the Peanut Innovation Lab is involved in gender and youth development initiatives as well as school feeding programs.

Technology: Unlike many fully commercial crops, peanuts (or groundnuts) are often seen as a subsistence crop in many countries. They are predominately rain-fed, grown on small household plots and typically managed and processed by women. 158F158F[159] Most of the peanuts produced by women are for household consumption with any remaining surplus sold to local markets to supplement family income.[160]

Over the past 30 years, many new varieties have been introduced, but they are often not available in the market or known to farmers.[161] The Peanut Innovation Lab supports national breeding programs, especially NARES, and collaborates with CGIAR Centers with a focus on building local capacities to create an ecosystem capable of breeding improved peanut varieties that reach farmers. On the research side, the Peanut Innovation Lab's partnerships with NARES across Africa is facilitated

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[157] "Research Output Dissemination Study: Examination of Dissemination Pathways in the Use, Adoption, and Scaling of Research Outputs of Feed the Future Innovation Labs;" C. Tyroler, "Gender considerations for Researchers Working in Groundnuts," Feed the Future, May 2019.

[158] "Research Output Dissemination Study," 5.

[159] *Id*.

[160] C. Tyroler, "Gender Considerations for Researchers Working in Groundnuts," *USAID*, May 2018; Rhoda Mofya-Mukuka and Arthur M. Shipekesa, "Value Chain Analysis of the Groundnuts Sector in the Eastern Province of Zambia," Working Paper No. 78, Lusaka, Zambia, *Indaba Agricultural Policy Research Institute (IAPRI)*, September 2013; The University of Georgia, PMIL, "Innovation Lab for Collaborative Research on Peanut Productivity and Mycotoxin Control Final Report," USAID, January 2018.

[161] Farid Waliyar, Dave Hoisington, and Jamie Rhoads, "Malawi Groundnut Seed Sector, Case Study Report," Feed the Future, Peanut Innovation Lab, University of Georgia, February 2021.

through the Groundnuts Improvement Network for Africa (GINA) which facilitates the sharing of germ plasm and parental lines, development of data, and sharing of technical knowhow across a network of breeders, agronomists, and molecular biologist in 15 African countries.

Some key features of peanut seed (open pollinated, low multiplication rate, poor germination rates, and short sorter shelf life) present challenges for dissemination and scaling by the private sector.[162] To overcome these challenges, the Peanut Innovation Lab and its research partners often work through community level partnerships. Some of the improved varieties are being multiplied and distributed through grassroots initiatives supported by farmer groups, NGOs, savings and loan groups, care groups, and faith-based organizations. Technology transfer agreements with these community groups are often not formalized.

Engagement through Community Organizations and NGOs: Two examples illustrate the use community-based pathways to disseminate improved varieties from the Peanut Innovation Lab and its research partners. In Uganda, NGOs are intervening by using farmer-saved seeds and community-based seed systems to bridge the gap between formal and informal seed systems. The adoption of a policy and regulatory framework for Quality Declared Seed (QDS) allowed for trained and registered farmer-led enterprises to participate and fill the quality gap between certified and home-saved seed.162F162F[163] NGOs stepped in to empower farmer groups in seed production, quality assurance, agribusiness management, and seed marketing.163F163F[164] The Peanut Innovation Lab worked with a NARES breeder and head of the groundnut improvement program and collaborated with ISSD Africa, an international community of practice, guiding innovation and addressing complex challenges of limited access to quality peanut seed.[165] Through this partnership the project worked directly with selected farmer groups to grow and sell improved seed varieties, allowing farmers to become recognized seed producers. In Senegal, a government program partners with CARITAS, a local NGO, funded on-farm trials with small seed pack distribution, where they are able to test three varieties and keep the one they liked best, enabling farmers to multiply the varieties they prefer. Though a lengthy process, these varieties are being adopted by some farmers.

Regarding legal considerations, peanut varieties do not generally garner intellectual property interest. Because of the unique features of peanut seed cited above, private seed companies have less interest in commercializing peanut varieties. Consequently, opportunities for royalty flows to breeders and NARES are scarce. Given these factors and that private licensing of varieties remain limited in most countries, both Peanut Innovation Lab and NARES generally consider their intellectual assets as public goods and only seek recognition for their contributions to improving livelihoods.

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[162] F. Waliyar, D. Hoisington, J. Rhoads,"Malawi Groundnut Seed Sector Case Study," *Feed the Future Innovation Lab for, University of Georgia*, 2021.

[163] A. Mastenbroek; G. Otim,; B.R. Ntare,"Institutionalizing Quality Declared Seed in Uganda," *Agronomy* 1475, (2021): 11.

[164] S. Anecho, "A Groundnut Value Chain and Market Systems Analysis in Uganda: An In-Depth Literature Review," Feed the Future Innovation Lab for Peanut, University of Georgia, 2023.

[165] "About," ISSD Africa, last accessed August 24, 2024.

Despite some success stories and limited alternatives, community-based models for seed multiplication and distribution also pose challenges, as it is hard to maintain seed quality and purity especially across multiple years.[166]

The Peanut Innovation Lab through its years of experience has been able to identify appropriate partners and pathways needed to further research and dissemination of improved peanut varieties. Through its use of community-based pathways, some key lessons have emerged. First, using community groups for dissemination can effectively address local needs by involving local actors who understand the context and have direct connections with end users. Second, close coordination can enhance the uptake and adoption of innovations, especially for crops that have less commercial value and are targeted for household consumption. Third, when working with community-based partners, emphasis on formally managing intellectual assets can stifle access and distribution thereby limiting impact on livelihoods.

3.5 Key Findings and Gaps

- While the current categories or thematic areas and phases of research provide a useful structure for tracking progress on IL outputs, a more nuanced classification approach may be required to assess the unique attributes of these innovations and relevant legal considerations. Legal considerations, in particular, often depend on the specific attributes of an innovation. The ILs tend to produce five main types of IAs, namely improved varieties, research publications, digital assets, novel devices and processes, and animal vaccines. Across these agricultural IAs, IP protection is rarely sought. However, greater focus on these particular IAs in institutional IA/IP management would help ensure more effective dissemination.

- Consultations conducted in the development of this study highlighted that issues beyond open access of data are becoming increasingly important with respect to data protection and use, as data are often aggregated in databases and artificial intelligence (AI) tools. These issues warrant further inquiry going forward.

- IL resources are primarily allocated to Phases I and II of research, with efforts focused on developing and testing technologies. Less effort is dedicated to transitioning these technologies into Phases III and IV, which require different skills, expertise, and institutional support. Additionally, the time and resources required to disseminate and scale these technologies can extend beyond the scope and funding timeline of the ILs. As a result, the actions needed to disseminate these technologies tend to be an afterthought. This gap highlights the challenges required to bring technologies to its end-users.

- ILs and their partners have varied dissemination approaches, which include (1) commercial, (2) public, (3) public-private, and (4) community-based partnerships. These dissemination

[166] Waliyar, "Malawi Groundnut Seed Sector Case Study."

and scaling pathways are often used in combination, depending upon the type of IA (e.g., crop varieties) and its market potential, which will lead to different legal instruments and structures for technology transfer based on the type of IA and partners in dissemination of the technology.

- There is a clear link between commercialization potential and IP protection, but it does not manifest as expected in the case of innovations developed by the ILs. Once an innovation reaches Phase III, where it is made available for uptake and has demonstrated commercialization potential or generated private sector interest, such as with hybrid seed varieties, there is often increased interest in seeking IP protection. However, ILs often do not seek IP protection even in these cases, most likely because their partners (CGIAR Centers and NARES) do not use IP to protect their IAs.

- In limited cases, IL technologies have been protected under IPR as seen in the PICS bag case study. In this case, a trademark was sought to protect the brand, and none of the ILs report pursuing patent protection for their innovations. Further, for dissemination of PICS bags, a combination of exclusive and non-exclusive licenses were issued. The PICS bag case study is an example of how public-private dissemination pathways can be successfully leveraged across countries.

- Regardless of IP status, technologies that have high potential for commercialization (commercial seed varieties, trademarkable storage products, vaccines, etc.) tend to generate more interest from the private sector, which takes a business-focused approach to dissemination and scaling. However, the private sector also tends to seek exclusive rights over technology, which often hinders public access or greater competition in the market.

- Dissemination of IL innovations is often done, at least in part, by IL partners such as CGIAR Centers and NARES under their own institutional policies, which tend to limit a purely commercial focus due to the public good nature of the innovations. Because current U.S. rules and policies, namely the BDA and the ADS, focus heavily on patents and their commercialization, this highlights the need for a more nuanced and flexible approach towards IAs developed by ILs, which could be a focus of USAID's new policy.

- Exclusive licenses for agricultural IAs can limit access to IL technology, which can be detrimental in the case of public goods. Semi-exclusive/limited exclusivity licensing agreements, as used by IL partners such as CGIAR Centers (see CGIAR IA Principles discussed in Section 4), could be emphasized, as they do not restrict access for public actors such as NARES.

- ILs also highlighted gaps in understanding the upstream policies governing technologies they produce. Without guidance, they tend to make decisions on IP/IA management on an ad-hoc basis without a uniform or comprehensive approach. Dissemination can be a lengthy and expensive process, and there would be significant benefit in sharing experiences, strategies, and lessons learned. Stakeholders noted the need for additional/ongoing support (beyond the project period) to maintain continuity and address

challenges in dissemination. A number of ILs also expressed an interest in greater communication and coordination across ILs.

IA MANAGEMENT POLICIES AMONG OTHER USG AGENCIES, DONORS, AND PARTNER INSTITUTIONS

The IA management policies of other partners and donors, including other USG agencies, CGIAR Centers, NARES, and other donors, such as the BMGF, can provide important insights for USAID. Other USG agencies focus primarily on commercial pathways for dissemination, while CGIAR and NARES focus on dissemination of technology through public and public-private pathways, and BMGF's licensing and commercialization strategy seeks to ensure access to important innovations by people in need.

4.1. USG Agencies

USG agencies that distribute grants and awards to external contractors generally have policies on IP management and commercialization/dissemination. Many of these policies are narrowly focused and still under development. However, some of them elaborate on rights and obligations under the BDA where USAID does not. There are some common policies among agencies that relate to BDA administrative requirements and USG rights regarding federally funded research, although many agencies have their own modifications. While other agencies do cover rights and requirements for award recipients, most policies surveyed also include guidance on how to commercialize and manage inventions. Some relevant policies include those from USDA, the DOE, the Department of Commerce (DOC), and the Department of Health and Human Services (HHS).

As well as ensuring alignment across USG agencies with similar external funding programs, USAID could incorporate the elements of some of these policies to further its own goals. Particular insights could be drawn from USDA's Working Group on seed variety development, DOE's guidelines for contractors to develop an IP management policy, and HHS's principles and guidelines for disseminating biomedical research.

U.S. Department of Agriculture

Both USAID and USDA sponsor research used to develop agricultural innovations for the public benefit. USDA funds research and development of agricultural science and technology through its National Institute of Food and Agriculture (NIFA),[167] which was created by the Food Conservation and Energy Act of 2008, commonly known as the Farm Bill.[168] USDA's IP management is based on its regulatory mandates, found in NIFA-17-005,[169] which include the BDA, the intangible property section of the Uniform Guidance for federal awards,[170] the implementing regulations of the BDA

[167] "About NIFA," NIFA, accessed August 23, 2024.

[168] "Intellectual Property Reporting," USDA, accessed August 23, 2024.

[169] "Federal Regulations for Intellectual Property," USDA NIFA-17-005.

[170] 2 CFR § 200.315; NIFA-17-005, § 3019.35; "Fact Sheet: Uniform Guidance (2 CFR § 200)," NIFA, USDA.

(37 CFR Part 401), and a sub-section of the Uniform Federal Assistance Regulations (7 CFR 3015) relevant to USDA. While USDA does have a policy specifically on patents, it only covers inventions made by government employees.[171] NIFA's grantees and contractors are allowed to retain ownership of inventions made under federally funded research and contract programs, while also giving the USDA a "royalty-free, nonexclusive, and irrevocable license to exercise, and to authorize others to exercise, the rights for Federal Government purposes."[172]

NIFA clarifies some of the BDA's administrative requirements in its Intellectual Property Reporting policy, particularly for patents and PVP.[173] In keeping with the BDA, NIFA requires that contractors report subject inventions, "two months after the institution learns of an invention"[174] and notify the agency whether they will elect title at least two years after reporting an invention.[175] Any patent or PVP application or issuance of a patent or PVP certificate should also be reported on iEdison, an interagency platform. While USAID contracts presumably also include a requirement to report patents on iEdison, nothing in the ADS 318 or other contract provisions cover PVP, which is another option for the protection of agricultural IPR that might not fall within the categories of patents, trademarks, or copyright.

Additionally, when a contractor declines title to an invention and an employee-inventor would like to elect title, USDA policy allows the employee-inventor to file an inventor certification form to request greater rights in the subject invention, in accordance with 37 CFR 401.9 and 35 U.S.C. 202(d) of the BDA.[176] USAID does not provide guidance on this situation in ADS 318, and it is unclear what the process is for an individual inventor to request title if a contractor chooses not to elect it.

USDA also has guidance on which innovations would benefit from commercialization. For example, USDA's policy on animal vaccines, which are developed both by in-house labs and federally funded contractors, is to "protect IP only if it enhances adoption of research outcomes, not income generation."[177] However, it only contemplates one pathway for technology transfer – through a commercial partner – meaning that the vaccine must be commercially viable.[178] This seems to undermine its public interest goal of protecting IP for the purposes of invention adoption alone. But in the case of a vaccine, perhaps private commercialization is the best pathway for dissemination. The Feed the Future initiative has other considerations regarding agricultural innovations that are less straightforward than vaccines and treatments, including encouraging

[171] USDA Departmental Regulation, No. 5700-001, re Patents.

[172] "Uniform Federal Assistance Regulations, Subtitle B--Regulations of the Department of Agriculture," 7 CFR § 3015.

[173] "Intellectual Property Reporting," USDA.

[174] "Intellectual Property Reporting;" *see* BDA provision at 37 CFR Part 401.14(c)(1).

[175] BDA provision at 37 CFR Part 401.14(c)(2).

[176] "Intellectual Property Reporting."

[177] "Technology Transfer: Animal Vaccines."

[178] *Id*.

agricultural development, increasing food security and resiliency, and promoting nutrition among vulnerable populations.[179]

In 2023, USDA formed a Working Group on Competition and Intellectual Property with the U.S. Patent and Trademark Office, Department of Justice, and Federal Trade Commission to clarify intellectual property issues in seed variety development.[180] This working group was created based on recommendations by a recent USDA study.[181] While it has yet to report on its findings, it may provide helpful insights into IP issues for agricultural innovations that are not necessarily covered in current USG policy. In addition to the working group, USDA is currently collaborating with the USPTO on several issues, including the balancing of incentives for agricultural innovation with promoting fair competition.[182] The USPTO also acknowledged the importance of other forms of IP in the agricultural sector and noted that PVP certificates, in particular, "strike a different balance from patents in permitting farmers to save seeds and for plant breeders to engage in continued research on the protected variety."[183] USAID can look to USDA policy in order to expand its own position on the use of PVP for certain agricultural innovations, as well as developing a procedure and policy for employee-inventor election of title.

Department of Energy

The Department of Energy's IP policy generally follows standard IP provisions for financial assistance awards, as outlined in the BDA, with certain modifications.[184] Because of the sensitive nature and value to the public of much of the DOE research, DOE has developed an extensive policy on when it may modify or restrict a contractor's ownership right under the BDA.[185] It has defined what constitutes "exceptional circumstances" in contracts associated with energy efficiency, renewable energy, nuclear waste disposal, cybersecurity, and other topics, as well as requiring specific U.S. manufacturing plans.[186] In such cases, DOE has determined that limiting contractor ownership rights would better promote the commercialization objectives of the BDA.[187]

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[179] *See* "About," Feed the Future.

[180] "USDA Launches Interagency Working Group on Competition and Intellectual Property in Seeds," USDA, March 23, 2023.

[181] "More and Better Choices for Farmers: Promoting Fair Competition and Innovation in Seeds and Other Agricultural Inputs," Agricultural Marketing Service, USDA, March 2023.

[182] Letters exchanged between the USDA and USPTO on March 7, 2023, between Katherine K. Vidal, Under Secretary of Commerce for Intellectual Property and Director of the USPTO, and Jenny Lester Moffitt, Under Secretary of Marketing and Regulatory Programs of the USDA.

[183] March 7, 2023 letter from Katherine K. Vidal to the USDA.

[184] "GNP-821-US, Grant & Cooperative Agreement: Research, Development, or Demonstration, Domestic Nonprofit Organizations, U.S. Department of Energy (DOE)," March 10, 2022.

[185] 37 CFR § 202(a)(2); 37 CFR § 401.3(e).

[186] "Determination of Exceptional Circumstances (DECs)," DOE's Office of the General Counsel, accessed August 23, 2024.

[187] "The Federal Government's Authority to Restrict or Eliminate Contractors' Rights to Federally-Funded Inventions in 'Exceptional Circumstances,'" *Knowledge Ecology International (KEI) Briefing Note* 2, May 1, 2020.

Otherwise, the DOE uses standard IP provisions for financial assistance awards.[188] USAID, on the other hand, has not provided for potential ownership rights modification in its ADS series.[189]

The DOE also has additional guidelines for the creation of an IP management system, such as for awardees of its Energy Efficiency & Renewable Energy (EERE) grant program. [190] This guideline is designed to enable funding applicants to independently create and submit for approval their own IP management plans.[191] The suggested elements include definitions, treatment of confidential information (such as through non-disclosure provisions or agreements), treatment of pre-existing (background) IP and "foreground" IP (such as subject inventions), a publication/dissemination plan (such as through a publicly available database), and a commercialization plan. The commercialization plan could be a centralized process, which might include bundling IP rights, a decentralized process, where individual team members would commercialize and license the technology, or a combination of the two. While USAID requires Feed the Future contractors to develop and submit their own scaling and dissemination strategy, suggesting the use of public-private partnerships,[192] it does not provide guidelines for creating an IP management plan. DOE's detailed guidelines for the creation of such a plan, including commercialization strategies, could provide a useful model for USAID.

DOE's Office of Technology Transitions (OTT) works on moving innovative technologies developed by the external research community, among others, into the commercial marketplace.[193] OTT's Technology Transfer Execution Plan (TTEP) for Fiscal Years 2021-2025 outlines a strategic framework to support DOE coordination of technology transfer and commercialization activities. The TTEP strategic framework defines four priority goals and outlines objectives and key activities under each goal. The four goals are: 1) accelerating commercialization of discoveries, 2) infusing private sector thinking into decision making, 3) advancing policies addressing commercialization barriers, and 4) developing effective partnerships.[194]

In informing an upstream policy for promoting the dissemination of innovations, USAID could draw from the DOE's EERE program IP management guidelines as a model to provide more direction to its contractors in planning for a subject invention's lifecycle. Similar to the DOE's office for

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[188] "GNP-821-US, Grant & Cooperative Agreement: Research, Development, or Demonstration, Domestic nonprofit organizations," Department of Energy.

[189] "Determination of Exceptional Circumstances Under the Bayh-Dole Act for Energy Efficiency, Renewable Energy, and Advanced Energy Technologies," *Department of Energy,* September 9, 2013; "Determination of Exceptional Circumstances (DECs);" The DOE has specific provisions for the Determination of Exceptional Circumstances (DEC) that may modify patent rights by the BDA at 37 C.F.R. § 401.3(e); *see* "Determination of Exceptional Circumstances (DECs);" "37 CFR 401.14 DOE Modified Patent Rights Clause," Office of Clean Energy Demonstrations. The DOE's policy further promotes domestic manufacture under the patent rights clause (37 CFR §401.14); "Intellectual Property Provisions (GNP-821-US), Grant and Cooperative Agreement Research, Development, or Demonstration Domestic Nonprofit Organization – U.S. Competitiveness," *Department of Energy,* March 10, 2022. .

[190] EERE 104.2: Intellectual Property Management.

[191] EERE 104.2: Intellectual Property Management.

[192] "Value Proposition: What USAID and the Private Sector Bring When We Work Together," USAID;"Feed the Future Innovation Lab for Soybean Value Notice of Funding Opportunity," USAID 14, July 6, 2021.

[193] "Technology Transfer Execution Plan," U.S. Department of Energy (DOE), Office of Technology Transitions.

[194] "Technology Transfer Execution Plan."

technology transfer, USAID could also expand its existing Innovation, Technology, and Research (ITR) Hub to assist external contractors with technology transfer, such as U.S. universities involved with FTF.[195] This could allow USAID to prioritize the goals of its agency in the dissemination process. Finally, USAID should give thought to whether it should outline any exceptional circumstances where the modification of ownership rights under the BDA would be justified.

Department of Commerce

DOC also has an active technology transfer office that could serve as a model for USAID. The DOC issues the BDA's implementing regulations (37 CFR Part 401) through NIST, which also oversees the Federal Laboratory Consortium for Technology Transfer (FLC).[196] Its IP management policy does not seem to deviate from the BDA. If there are any agency-specific modifications, they seem to be done on an ad-hoc basis through the DOC's Technology Partnerships Office.[197] This office facilitates technology transfer by connecting in-house labs with external partners, as well as helping external partners with invention development and commercialization, particularly patenting and licensing.[198] It is similar to the technology transfer offices in many U.S. universities surveyed.

As a new member of the FLC, USAID could direct its external contractors to take advantage of the FLC's free educational resources center to learn about IP management and options. While this is geared primarily towards federally-owned labs and government-owned IP, it could be helpful to outline the usefulness of different IP protections. FLC's goal is to facilitate the transfer and licensing of government inventions to outside partners for dissemination and public benefit.[199] The FLC Learning Center offers modules on patents, trademarks, copyright, NDAs, licensing agreements,[200] among others.[201] One module discusses alternative options to patenting government inventions, namely through trade secret protection, and weighs the legality of government-owned trade secrets against U.S. FOIA obligations.[202] However, there are no resources focused on the unique issues of agricultural innovations or dissemination pathways. USAID could suggest that these modules be developed.

In 2023, NIST tried to clarify the USG's march-in rights, particularly regarding pharmaceuticals, through its Interagency Working Group for Bayh-Dole.[203] NIST proposed revising the BDA so that march-in rights "shall not be exercised exclusively based on the business decisions of the contractor

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[195] *See* "Innovation, Technology, and Research," USAID.

[196] Bethany Loftin, "Draft Interagency March-In Framework," U.S. Department of Commerce, National Institute for Standards and Technology (NIST), December 2023.

[197] "An In-Depth Look into Intellectual Property: Part Two," NIST, effective January 21, 2020.

[198] "About the Technology Partnerships Office," NIST.

[199] "Learn how the FLC supports Federal Labs," FLC Services.

[200] The Technology Transfer Commercialization Act of 1998 (H.R.4859), amending the Stevenson-Wydler Act, allows government labs to license a federally owned invention developed under a CRADA that has already been patented.

[201] "FLC Education Center," FLC Learning Center.

[202] "DoD T2 Training: Alternative Options for Protecting and Licensing Government Inventions," Courses, FLC Learning Center.

[203] "NIST Releases for Public Comment Draft Guidance on March-In Rights," NIST, December 7, 2023.

regarding the pricing of commercial goods and services."[204] It most notably addressed the question of whether an agency could exercise this right based on excessively priced commercial goods. This was prompted by concerns about the affordability of prescription drugs developed with federal funding, particularly HIV/AIDS treatments.[205] However, it is not clear whether this reflects the NIST's IP policy or is a general effort to clarify the BDA.

NIST also approaches the protection of IP as a business and security decision.[206] Its policy on commercialization and technology transfer policy is laid out in its series on "An In-Depth Look into Intellectual Property," which covers topics such as strategic goals of IP and technology transfer in general.[207] NIST states that IP considerations are important for technology transfer, which it defines as "… the overall process by which NIST knowledge, facilities, or capabilities in measurement science, standards and technology promote U.S. innovation and industrial competitiveness in order to enhance economic security and improve quality of life."[208] However, its main focus seems to be on patents, and NIST encourages its contractors to file them for "commercially valuable inventions."[209] While USAID does discuss IP issues in ADS 318, it could develop a more user-friendly policy where contractors could learn about different IP and technology transfer options, especially those geared towards the agricultural sector.

Department of Health and Human Services

Although the NIH does not have an extensive description of IP management, it provides certain BDA interpretations that USAID is missing, namely an employee-inventor ownership policy, exceptional circumstances to the modification of BDA ownership rights, and a march-in rights policy. NIH is a subdivision of the U.S. Department of Health and Human Services (HHS), and it outlines IP ownership in its technology transfer policy. NIH generally allows contractors to request title to any inventions created outside of an agency-owned lab, in keeping with the BDA.[210] Similar to USDA, NIH also allows an employee-inventor to retain title to an invention if it serves the public interest and/or if the invention could be commercialized without the involvement of the NIH. [211] NIH also provides a non-exhaustive list of situations under which the agency might take title if a contractor does not elect title, including if the invention is closely connected to the agency or if the invention has commercial or public health value to the government. [212] In terms of march-in rights,

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[204] "Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights," NIST, 88 Fed. Reg. 85593; "March-In Rights Under the Bayh-Dole Act: Draft Guidance," *Congressional Research Service*, February 2024.

[205] "March-In Rights Under the Bayh-Dole Act: Draft Guidance,"

[206]"An In-Depth Look into Intellectual Property: Part Two."

[207]"An In-Depth Look into Intellectual Property: Part One," *NIST*, January 10, 2020

[208] *Id.*

[209] "An In-Depth Look into Intellectual Property: Part Two."

[210] See "PHS Policy Regarding Inventor Requests to Acquire Title in Extramural Inventions," *United States Public Health Service Technology Transfer Policy Manual*, Chapter No. 603.

[211] *Id.*

[212] *See id.*

NIH has clarified that it would not exercise these rights based solely on the price or affordability of the product.[213]

4.2. BMGF IP Management Policies

BMGF's global access policy, which informs its IP management, could provide another model for USAID's evolving policy. In 2022, the foundation spent $775 million on global growth and opportunity, which includes agricultural development (primarily in sub-Saharan Africa and South Asia), nutrition, digital public infrastructure, education, financial systems, and water sanitation and hygiene.[214] Many ILs funded by USAID also receive funding from BMGF for innovation development. BMGF is one example of a donor that has tried to balance the development and dissemination of public goods with practical IPR considerations. Similar to the BDA, BMGF's goal is to fund innovations that ultimately reach the market and benefit the people who need them most.[215] BMGF's global access policy requires grantees to make their outputs "widely available at an affordable price, in sufficient volume, at a level of quality, and in a time frame that benefits the people the foundation is trying to help."[216] However, BMGF's policy also allows for the commercialization of these products as long as they are still available to people in need,[217] providing the option for IPR protection while supporting and sustaining global access objectives.

Grantees typically own the funded innovations, but BMGF uses several tools to manage potential IP assets to achieve policy objectives. Before funding is granted, BMGF's IP team will negotiate global access commitments, including quantity, price, distribution, data management, third party IP rights, and in some cases licensing and Principles for Responsible Investment (PRIs).[218] BMGF can require these commitments from grantees as well as partners who disseminate the technology.[219] Adopting a similar, more detailed approach to grant management may be a consideration in the formulation of USAID's policy.

While BMGF's mission remains consistent, its global access policy can be flexible. Obligations are negotiated on a case-by-case basis depending on a number of factors, including BMGF goals, project duration and complexity, partnerships, the nature of background IP, and potential uses of funded IP, among others.[220] Agreements with grantees and partners under the policy may include "a basic Global Access clause, [with] the foundation taking a non-exclusive [humanitarian] license to the Funded IP, or a requirement that the partner satisfy certain specific Global Access

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[213] "March-In Rights Under the Bayh-Dole Act: Draft Guidance."

[214] "Our Work and How We Work," Bill and Melinda Gates Foundation.

[215] "Global Access Statement," Bill and Melinda Gates Foundation; Catherine Jewell, "IP and Philanthropy: the Gates Foundation's approach," *WIPO Magazine*, August 2013.

[216] "Global Access," BMGF.

[217] "IP and Philanthropy: the Gates Foundation's approach."

[218] Ibid; Developed by a group of institutional investors at the UN, the Principles for Responsible Investment incorporate ESG issues and promote sustainable growth. *See* "About the PRI," UN Principles for Responsible Investment.

[219] "Global Access Statement."

[220] *Id*.

milestones."[221] Again, these details could be integrated into a possible USAID policy on agricultural IA management.

Similar to the non-exclusive, royalty-free license required by the BDA, BMGF's humanitarian license is "nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license" for "essential background technology." BMGF reserves this license only where it deems it necessary to ensure achievement of Global Access.[222] Grantees can also license products to third parties as long as this does not interfere with their Global Access obligations.[223] While exclusive licenses to essential background technology or other funded outputs are sometimes permitted, this must be done "in a manner that does not limit the scope of the humanitarian license" or limit global access commitments.[224] In an interview with one BMGF stakeholder, the humanitarian license was sometimes negotiated to accommodate exclusive licenses with time limitations, but this seems to be something that is considered under exceptional circumstances. For example, an agricultural drug company (Corteva) was given an exclusive license for five years. Some IL innovations are also subject to a humanitarian license because of previous funding by BMGF, such as PlantVillage and the PICS bags.

BMGF's policy recognizes management of IP as a critical aspect of global access and acknowledges that IP protection may be needed for some technologies to ensure broad access to funded technology. It requires that grantees complete an IP report upon request for the Foundation to identify any existing or future IP related to the project.[225] To facilitate communication and monitoring of partners' commitments, especially regarding relevant IPR and related agreements, the foundation has a Global Access Portal where partners must submit their IP Reports.[226]

Based on consultations conducted in the development of this report, BMGF's policy also has gaps, particularly regarding agricultural technology. For example, it does not address some of the challenges related to scaling agricultural IAs discussed in Section 3, including the issues that partner institutions like the NARES face in disseminating technology and securing an adequate and reliable revenue stream.[227] Further, while BMGF must make some concessions to the private sector, especially seed companies, in order to disseminate certain funded technologies, its policy seems to be unclear on how to balance this aspect of commercialization with its global access goals. Even though BMGF's policy has allowed for exclusive licenses, consultations highlighted that questions similar to those noted in Section 2 have arisen regarding whether use of exclusive licenses may limit BMGF's ability to ensure broad access to the funded innovations. Discussions

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[221] *Id.*

[222] "IP Report Sample," BMGF.

[223] "Global Access Statement."

[224] "Humanitarian License: Frequently Asked Questions," Bill and Melinda Gates Foundation.

[225] "IP Report Sample," BMGF.

[226] "IP Report Sample," BMGF.

[227] Stakeholder consultations conducted under the project (notes on file with the authors).

are ongoing within BMGF to review the current IP management policies and their suitability for agricultural innovations.

4.3. IP Management Policies of CGIAR Centers and NARES

Public sector agricultural research and plant breeding are dominated by CGIAR Centers and NARES. ILs work with CGIAR Centers and NARES in different capacities. The internal policies and procedures of CGIAR Centers and NARES both have implications for the work of the ILs and offer lessons to consider in the context of USAID's policy approach on IA/IP management.

CGIAR Centers are focused on managing international gene banks and developing new improved technologies, and NARES are responsible for adapting and developing technologies suited to local conditions. CGIAR Centers have a common institutional framework that guides IA management and dissemination strategy; however, individual Centers have their own policies as well. Approaches can vary based on factors such as crop type and private sector engagement. NARES have their own strategies based on national priorities and are mostly engaged in agricultural research and other activities to the benefit of farmers.[228] NARES are also increasingly using licensing to disseminate technology and improve revenue generation to carry out further public research and breeding (discussed under public-private pathways).

Particularly in the case of improved varieties, although other technologies may be relevant as well, ILs work through partnerships with public entities such as CGIARs and NARES. ILs typically prioritize working through the public sector to disseminate products like improved varieties with low commercial value such as open pollinated crops (e.g., cowpea, millets and groundnuts) or vegetatively propagated crops (e.g., cassava, sweet potatoes).[229]

CGIAR Centers

CGIAR Centers are guided by CGIAR Principles on the Management of Intellectual Assets (CGIAR IA Principles)[230] and their implementation guidelines.[231] These are instruments based on the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA),[232] which focuses on food security and sustainable use and exchange of Plant Genetic Resources for Food and Agriculture (PGFRA). The CGIAR IA Principles and implementing guidelines prioritize maximizing global public access and use of CGIAR IAs. These instruments are customized by CGIAR Centers like the CIMMYT,[233] the International Institute of Tropical Agriculture (IITA),[234] and the

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[228] D. Byerlee and J. Lynam, "The Development of the International Center Model for Agricultural Research: A Prehistory of the CGIAR," *World Development* 105080, November, (2020): 135.

[229] "Research Output Dissemination Study."

[230] "CGIAR Principles on the Management of Intellectual Assets," CGIAR, March 7, 2012.

[231] "Implementation Guidelines for the CGIAR Principles on the Management of Intellectual Assets," CGIAR, 2013.

[232] "International Treaty on Plant Genetic Resources for Food and Agriculture," FAO.

[233] "CIMMYT Intellectual Property Policy," CIMMYT, 2009.

[234] "Policy of the International Institute of Tropical Agriculture on Intellectual Property/ Assets," IITA, 2012.

International Potato Center (CIP)[235] through their own institutional IP or IA Policies and other instruments such as material transfer agreements and licensing agreements to guide the dissemination of their IAs. Though customized, the individual CGIAR Center IP policies and licensing agreements remain aligned with the ITPGRFA and CGIAR IA Principles. Currently, the CGIAR Centers are working on creating a consolidated licensing policy under One CGIAR.

In practice, CGIAR Centers have not registered varieties at the national level, which highlights the role of national partners like the NARES and private sector in registering varieties on national variety lists and commercializing these varieties. In many countries, registration is a prerequisite for commercialization and dissemination at the national level. National level variety registration has been a focus of the NARES, while commercialization has been the focus of seed companies, even though these lines blur. Using international technology developed by the CGIAR Centers for national level registration and commercialization also gives rise to questions of control over technology and appropriate licensing arrangements between the NARES and private sector. In some cases, there may be friction between the NARES and private sector in national dissemination, particularly since the NARES are very resource constrained.

Further, CGIAR Centers often lose track of their varieties after they are registered at the national level by a local partner, as confirmed by stakeholders under previous research conducted by NML.[236] Although the CGIAR practice of leaving national registration of varieties to other partners may be changing (recently, CIP registered several of their varieties in Kenya and Mozambique with the purpose of controlling and tracking the territory in which the varieties are licensed), this highlights the importance of enhanced tracking policies and procedures.

Further, with regional seed rules and regulations in different stages of development and implementation under several different RECs and continental efforts under discussion, CGIAR Centers are considering how to leverage partnerships that could facilitate wider dissemination in regional and continental markets. For instance, CIMMYT has registered hybrid maize varieties in the Common Market for Eastern and Southern Africa (COMESA) Seed Variety Catalogue, meaning that such varieties could, in theory, be disseminated in all 21 COMESA Member States. The nature of regional seed rules under the Economic Community of West African States (ECOWAS) has also allowed most CGIAR Centers, including CIMMYT, CIP, IITA, the International Center for Agricultural Research in the Dry Areas (ICARDA), Africa Rice, and the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), to register varieties in the West African Catalogue of Seed and Plant Varieties.

The CGIAR IA Principles, implementing guidelines, and individual CGIAR Centers' IP/IA Policies' emphasis on public use and global access to IAs leads CGIAR Centers to disseminate technologies largely under MTAs based on the Standard Material Transfer Agreement (SMTA) under the

[235] "International Potato Center Intellectual Property Rights Framework Policy," CIP, December 2016.

[236] "Legal Review and Analysis of the Implementation of the Variety Identification Number at the National and Regional Levels," New Markets Lab, May 2022 (on file with authors).

ITPGRFA.[237] MTAs are used when parties reach mutually acceptable agreements with respect of the handling, use, commercialization, and liabilities when using a specific type of proprietary technology. In general, MTAs include a provision that establishes the short-term use of molecular technologies in genetic engineering research when very little or no revenue is needed for their use. The commercialization of these outputs can require the execution of a licensing agreement.[238] MTAs can take different forms, ranging from letters accompanying a seed shipment to carefully negotiated contracts. However, if not drafted appropriately, they could restrict further research and impact dissemination. MTAs have been used in different situations and for various outputs. For instance, an indigenous community that has entered into an MTA can lay claim to genetic material before sharing it at large. Another example is seed banks that use MTAs to either share or sell the seeds they collect from indigenous communities or from small, independent breeders.[239] MTAs can be used as proof of agreed-upon terms in case seeds from the collection fall into the hands of someone who would use them in a breeding project that would later be protected with patents or plant breeders' rights.[240]

In addition to the NARES, the private sector also plays a crucial role in wider dissemination of public breeding results (i.e., private delivery of public technology produced by CGIAR Centers), especially where there is a high commercialization potential for the IA. This has given rise to an increased use of licensing agreements with the private sector, which will depend upon dissemination strategy, nature, and type of crop.

In total, only 33 of these licenses were issued in 2022, and 31 of them were issued by CIMMYT in pursuit of national varietal registration and commercialization of its hybrid maize varieties.[241] CGIAR Centers like CIP have previously preferred to disseminate their varieties through NARES, which then enter into licensing agreements with seed companies. However, more recently, there is increasing interest within most CGIAR Centers, including CIP, to explore limited exclusivity licensing agreements with the private sector in compliance with the CGIAR IA Principles.

Consultations with CGIAR Centers like CIMMYT, CIP, and IITA revealed that limited exclusivity licensing agreements with the private sector often contain terms to ensure maximum public use of the IA, such as disclosure requirements (e.g., production plans that show intent to produce the varieties) and terms that protect the interests of smallholder farmers like packaging in small packs. While CGIAR Centers sometimes use licensing agreements to disseminate IAs through commercialization by the private sector, the CGIAR IA Principles require that such licenses contain some limitations (e.g., on exclusivity) and can be justified as necessary to improve the IA or widen the scope of impact on target beneficiaries (smallholder farmers).[242] As per the CGIAR IA

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[237] "Standard Material Transfer Agreement, Resolution 1/2006," FAO, June 16, 2016; *see also*, "SGRP, Guide for the CG Centers' Use of the Standard Material Transfer Agreement," *Biodiversity International* 2, 2009.

[238] "Operations and Policy Manual," Feed the Future Innovation Lab for Collaborative Research on Grain Legumes, 21.

[239] "A Guide to Seed Intellectual Property Right," Organic Seed Alliance.

[240] *Id*.

[241] "Intellectual Assets Management Report, 2022," CGIAR SB/M27/EDP2, November 3, 2023.

[242] Section 6.2 of the CGIAR IA Principles.

Principles, the licensed IA should also remain available for use by public research organizations like NARES, for non-commercial research purposes. These considerations and limitations could be important in the context of USAID policy as well.

For crops such as Irish potato, which has high commercialization potential, CIP has noted that management of IAs is important to give clarity to the private sector to further invest in the commodity. Ordinarily, CIP transfers both hybrid and OPV varieties to NARES through SMTAs, which go on to license varieties to seed companies. However, companies are increasingly interested in entering into limited exclusivity agreements (as opposed to absolute exclusivity over the commodity, which was their previous demand), possibly expanding the role of the private sector and use of licensing agreements.

In addition to serving as a legal tool for commercialization and dissemination, licensing agreements can be used to transfer royalties from the profits earned by the private company to the R&D used to produce the public good (back to the CGIAR Center or NARES).

With interest in keeping their IAs in the public realm, CGIAR Centers also rarely consider IPR over their technologies. For instance, in 2022, only six patents were obtained by CGIAR Centers, including one by ICRISAT, four by the International Rice Research Institute (IRRI), and one by CIP.[243] Similar to issuance of limited exclusivity licenses, the CGIAR IA Principles require that CGIAR Centers only apply for IPR when necessary for the further improvement of the IA or to enhance the scale or scope of impact on target beneficiaries. The CGIAR Principles require the interested CGIAR Center to provide information and justification to the CGIAR System Organization on how such IPR will fuel dissemination, including a strategy on global access and impact.

In the same spirit, the CGIAR Principles strongly discourage centers from receiving IPR protected by third party IAs under restricted use agreements unless there are no viable alternatives available.[244] This could limit some forms of engagement with the ILs and the applicable dissemination strategies if such IA is protected. While restricted use agreements allow CGIAR Centers to acquire and use cutting-edge technologies that would otherwise be inaccessible, the dissemination of resulting products and services often hinges on the restrictions imposed by the technology provider, which could confine the geographic scope of dissemination and impose additional end-user requirements in the form of additional approvals and/or administration obligations. As a result, there have been very few restricted use agreements by CGIAR Centers, with only two from 2022 (one by CIMMYT and the other by ICARDA).

CGIAR has also built in a monitoring and evaluation system, whereby it publishes an annual CGIAR IA Management Report pursuant to the CGIAR IA Principles. This reporting is based on following six elements laid out in the CGIAR IA principles: (1) CGIAR annual engagement with international regulatory frameworks; (2) farmers' rights; (3) access and benefit sharing; (4) use of limited exclusivity agreements; (5) use of restricted use agreements; and (6) intellectual assets

[243] *Id*.

[244] Section 6.3 of the CGIAR IA Principles.

management under One CGIAR. According to the 2022 CGIAR IA Management Report, CGIAR Centers filed five patent applications in 2023, with one patent granted, and entered into 33 limited exclusivity agreements and two restricted use agreements.[245] Stakeholders have noted that this reporting is mostly focused on limited exclusivity agreements with private companies, which have to be negotiated and reported.

NARES

A growing number of NARES have developed, or are in the process of developing, IP policies, even though, like the ILs, many NARES do not comprehensively seek IP protection for their research outputs. While most NARES lack an institutional framework to guide the dissemination of their technologies, a few have developed IP policies, which could also be named IA Policies, since the NARES are also not claiming IP for many innovations. Existing IP Policies include provisions on co-ownership of technologies when developed with the financial or capacity support of other partners (such as CGIAR Centers and private companies), obtaining IPR for NARES' technologies, description of licensing agreements that the NARES can issue, institutional framework/authorities on IP management, and confidentiality, commercialization, disclosure, reporting, and dispute settlement provisions. They may also include provisions on terms of IP ownership, capacity building, and collaborative research.

The NARES have varied approaches to dissemination of their agricultural research and technologies.[246] NARES primarily focus on producing new and improved varieties, which could be protected under PBR if the relevant conditions are met.[247] NARES' strategies on technology dissemination focus on delivery of agricultural research outputs to target beneficiaries (smallholder farmers) in an accessible manner as well as commercialization of IAs produced by them. For both acquired IAs received under MTAs from CGIAR Centers that the NARES have adapted and their own developed IAs, the NARES are increasingly looking to licensing agreements with the private sector as a pathway for technology dissemination.[248] The type of licensing agreement used depends upon the NARES and type of commodity/crop. Through licensing agreements, the NARES transfer the right to produce, market, and sell varieties registered by them (or their designee). While licensing agreements are often used by the NARES to commercialize already-registered varieties, the NARES can also license the right to register a variety at the national or regional levels to the private sector.

Licensing agreements issued by NARES often contain use rights and are not based on IPR, although this depends both on whether the NARES have claimed IPR for their IAs and on the national legal framework that guides the NARES' licensing practices, institutional interests, and dissemination

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[245] *Id.*

[246] Katrin Kuhlmann and Adron Naggayi Nalinya, "Guide on Flexible Licensing Approaches and Options for NARES," Working Paper by IRRI, CIP, and New Markets Lab, January 2024.

[247] NARES have reported that they have protected technologies under PBR, patent, trademarks, copyright and know-how. ARC have licenses PBR which are licensed globally.

[248] "Annotated Guide on Flexible Licensing Models and Agreements," New Markets Lab, Seeds2B Africa, and Syngenta Foundation for Sustainable Agriculture, 2019.

strategy. For instance, the Tanzania Agricultural Research Institute (TARI) in Tanzania is mandated by law to only issue licenses for protected technologies. This has proven to be a bit of a challenge, since TARI does not have the resources, financial or human, to register and maintain IPR for its innovations. Other NARES, including the Kenya Agricultural Livestock Research Organization (KALRO), the Agricultural Research Council (ARC) in South Africa, the National Agricultural Research Organisation (NARO) in Uganda, and the Zambia Agricultural Research Institute (ZARI) are licensing plant varieties without PBR. Licenses may be exclusive, semi-exclusive, or non-exclusive, depending upon the NARES' policy and type of commodity/crop. While the private sector tends to prefer exclusive agreements that allow companies to maximize revenue, NARES may also prioritize strategies that protect marginalized groups. For example, licensing agreements entered into by ARC in South Africa contain provisions on black economic empowerment (BEE), with provisions requiring companies to sell varieties to black-owned companies to ensure that the technologies also reach disadvantaged smallholder farmers. Further, ARC has also established partnerships with organizations like the African Agricultural Technology Foundation (AATF) to expand their reach to smallholder farmers beyond South Africa.

For commodities with high commercial value, most NARES focus on engaging with seed companies to explore wider markets for a variety. Licensing royalties can help generate more revenue for NARES, which are often grossly underfunded. KALRO has been quite successful in using licensing agreements, and, since 2001, the institution has earned an average of USD 200,000 per year in royalties for licensed varieties.[249] Royalty terms can depend upon the kind of agreement, whether a variety is protected under PBR, and the crop. With regard to disseminating NARES varieties to regional or global markets, licensing agreement terms often set out territories for seed companies to disseminate the varieties. ARC in South Africa uses these terms to protect smallholder farmers within the country by identifying a market they would want to export to and leaving these out of the scope of the licensing agreement. Licensing agreements could also contain terms to prevent unauthorized production of seed. For commodities that are essential for food security and may not necessarily have high commercial value, NARES may use different strategies to encourage production and wider dissemination. For example, for varieties like sweet potato, the ARC focuses more on R&D and building capacity of farmers to grow those varieties.

Among African NARES, ARC in South Africa holds the most IPR, with more than 400 varieties covered under PBR. KALRO has also claimed PBR protection for some of its varieties, and over 60 of its tea varieties are covered under PBR (about eight PBR applications are pending for maize hybrid varieties). NARO has signaled interest in protecting its varieties under IPR, but the national legal framework on PBR is incomplete, with an Act in place without implementing regulations. Moreover, registration for some forms of IPR, like PBR, comes at an expense that some NARES, which are already resource-constrained, may not be able to afford.[250] The effectiveness of licensing as a dissemination strategy by the NARES will largely depend upon its institutional management

[249] New Markets Lab and Syngenta Foundation for Sustainable Agriculture, "Licensing of Public Plant Varieties: The Case of KALRO," Seeds2B Africa, December 2022.

[250] K. Kuhlmann, A.N. Nalinya, I. Sawe,and C.O. Ojiewo, "Synthesis Report on TARI's Licensing of Public Plant Varieties," New Markets Lab and the International Maize and Wheat Improvement Center, 2023 (Publication Forthcoming).

framework. While KALRO has been relatively successful, for example, it has developed an institutional approach and capacity over at least a decade of licensing.[251] A number of stakeholders also noted lack of management to deal with issues such as multiple stakeholders applying to register the same variety, which has become a legal issue in Kenya where KEPHIS has been unable to identify the rightful rightsholder of the variety in the case of common beans.

4.4. Key Findings on Practices of Other USG Agencies, Donors, and International Partners

In light of the lessons presented in this report, USAID could consider a more comprehensive IP management policy and guidelines, drawing lessons from other USG agencies, international partners, and donors. In particular, this policy could benefit from examples of other donors, such as BMGF, and institutions, such as CGIAR Centers, on how to balance commercialization and dissemination strategies with a focus on agricultural public goods. Other insights underpinning the recommendations that follow include:

- Other USG agencies build on BDA provisions beyond the scope of what is covered in ADS 318. These provisions clarify agency position on employee-inventor title retention, ownership rights, waiver of title, or USG march-in rights.

- Some USG agencies take more detailed or nuanced approaches to the scope of IPR covered under their policies. For example, USDA's IP policy addresses agricultural innovations like plant and seed varieties and animal vaccines. This recognition of particular forms of agricultural technology is important, but it also underscores a gap with regard to a broader set of agricultural innovations that may require alternative pathways for dissemination. USDA has also established the Working Group on Competition and Intellectual Property, which is addressing IP issues related to seed variety development. This group could be an important forum for raising some of the issues presented in this report.

- Many USG agencies have established a technology transfer office that supports dissemination federally funded technology. However, current USG rules, policies, and guidelines are not tailored to agricultural technology, which has unique characteristics and will depend upon dissemination pathways beyond the commercial pathway. USG policies are designed to recognize commercial innovations, such as patented goods in high market demand, but they are not suited to innovations with a strong public good dimension. Across all agencies, focus is placed mainly on the innovation itself and not on dissemination and scaling pathways. These biases in USG policy could lead to protection and dissemination of a narrow set of agricultural innovations, including commercially viable plant varieties and vaccines, but they could make it more difficult to recognize and scale other innovations, such as plant varieties for neglected crops.

[251] "Licensing of Public Plant Varieties: The Case of KALRO;" *see also*, New Markets Lab and Syngenta Foundation for Sustainable Agriculture, "Case Study on KALRO Model Plant Varieties Licensing Agreement," Seeds2B Africa, February 2020.

- While most USG agencies fund research to benefit the public, their policies on the commercialization and dissemination of IP tend to be largely business-related. For example, USDA's policy explicitly references a commercial/private pathway for the dissemination of animal vaccines, but it does not incorporate alternative dissemination pathways for other types of technology.

- Under public and public-private dissemination pathways, IL partners such as CGIAR Centers and NARES are central partners, although these partners feature in all of the dissemination pathways studied. CGIAR Centers are guided by the CGIAR IA Principles, which focus on global public access and use of CGIAR IAs. CGIAR Centers transfer technologies under MTAs which include terms on handling, use, commercialization, and liabilities of using a specific technology. If a technology is commercialized, CGIAR Centers may opt to use licensing agreements, although this is not yet a prevalent practice. In many cases, CGIAR Centers will allow the NARES to undertake licensing and benefit from the resulting royalty payments. CGIAR Centers' policies tend to be more tailored to the dissemination and management of agricultural IAs than USG policies, providing an opportunity to draw lessons from these practices.

- Donors like BMGF also have policies on management of IP and IA assets, including securing global access commitments from both grantees and commercial partners, third party IP rights, sustainable investment practices, and licensing, with BMGF often calling for a royalty-free, non-exclusive humanitarian license to ensure that funded technologies reach their intended beneficiaries.

- Licensing models are prevalent in agricultural dissemination strategies, and it is important to keep in mind that licenses can be used in different contexts, such as providing rights to funders and donors (e.g., USAID's use right and the humanitarian licensing model used by BMGF), encouraging dissemination through the private sector (the semi-exclusive licensing models used by some of the CGIAR Centers, which currently do not carry royalty payments) and raising revenue for public institutions (the licensing models increasingly used by the NARES to commercialize plant varieties, which do have royalty obligations and also encourage private sector commercialization). KALRO, ARC, NARO, and ZARI are all relying on licensing for technology dissemination and revenue, and they have developed detailed IP policies that cover protection of their own innovations and licensing (in reality, these may be better designed as IA policies, since many of their innovations are not protected under IP).

- BMGF requires grantees to submit a report identifying relevant IP and monitoring whether global access commitments are being followed. IL partners such as CGIAR Centers have also adopted monitoring and evaluation systems that provide useful models. The CGIAR publishes an annual CGIAR IA Management Report, pursuant to the CGIAR IA Principles, which requires reporting on engagement with international frameworks, the promotion of farmers' rights, public access and information sharing, limited use of exclusive agreements, restricted use agreements, and IP management. While USAID has an annual reporting requirement, it could consider further elaborating these practices.

While USAID's ADS covers many aspects of the BDA, it could integrate and adapt provisions from other USG policies and IP management guidelines. Where these agencies are silent on issues of public good dissemination and licensing structure, USAID could be a first mover within the USG and could also draw lessons from other partners and donors, such as the CGIAR Centers and NARES and BMGF's global access commitments. Licensing practices across their different applications require particular focus, given their relevance to the innovations produced and their distribution. These are incorporated into recommendations for USAID policy in the section that follows. Other aspects relating to intellectual assets require further investigation, including data rights and artificial intelligence, where practices and law are in flux, co-funded projects, classification of IAs, and regulatory and policy training and capacity transfer models, which are discussed in greater detail in the concluding section.

RECOMMENDATIONS

Based on the findings presented above, recommendations follow related to upstream policies, the work of the ILs, and lessons learned from other agencies, donors, and partners. Taken together, these could form the basis for a USAID policy on agricultural technology management and dissemination.

5.1. Recommendations for Upstream Management of Publicly-Funded IA

USAID policy could be expanded to better address the agricultural focus of GFSS projects, IAs developed by the ILs, and unique characteristics of the agricultural sector. A number of recommendations stem from the study that could help inform an institutional policy for USAID on IA dissemination and management for the ILs and other partners.

- USAID should adopt an institution-wide policy or provide guidance on management and dissemination of agricultural IAs developed under its projects. ADS 318 is limited in its focus on patent, copyright, and trademark protection, which overlooks other types of IP related to the agricultural sector. In the context of agricultural development and food security, many publicly-funded innovations are not protected under IPR at all, as the experiences of the ILs highlight.

- Perhaps most notably, ADS 318 (like the BDA) is focused primarily on the innovation itself and does not consider how it will be disseminated. This emphasis is evident in university policies as well, and it results in the prioritization of patented innovations based on the assumption that providing inventors with this protection will drive dissemination of commercial innovations. This raises important questions with respect to agricultural innovation and food security (and more broadly with respect to challenges like climate change as well), where dissemination in developing economy markets is of paramount importance and cannot be achieved through commercial dissemination of patented technology alone. A number of policy considerations are important here, which are addressed below, including how to address the question of licensing to third parties (especially the private sector, which will favor market exclusivity), whether and how dissemination pathways that engage a range of partners should be encouraged (in particular, the NARES will remain an important partner in dissemination of agricultural innovations), and where royalty revenue can appropriately be claimed for publicly funded innovations and how it should be distributed.

- ADS 318 is applied on a contractual basis, which may lead to inconsistencies in its application. Based on the BDA and ADS 318, USAID could require funding recipients to report on technologies that are not protected under IPR or that are not taken up for commercialization. USAID could require that its grantees consider additional coordination, reporting (including IA screening and IP capture, coordination and compliance requirements), and policy objectives (e.g., balancing public good impact with commercial gain and bolstering the capacity and resources of local partners) in order to increase the success of agricultural technology dissemination.

- Universities encourage and pursue protection of technology based on commercial potential. If a university does not pursue commercialization of the IA, then it will defer the rights back to the inventors of the IP. Further, universities tend to focus on pursuing commercialization of IAs in certain sectors, such as pharmaceuticals, which can leave a number of IAs produced by ILs outside of university IP/IA management frameworks. In this case, USAID could establish an accountability system for funding recipients to report on technologies it has commercialized. This could be similar to the monitoring and evaluation system established by the CGIAR Centers.

5.2. Recommendation on IL Policies and Practices to Disseminate and Scale IA

- Drawing from IL practices, USAID should consider providing guidance on different pathways for the dissemination of agricultural innovations, including suggesting protection mechanisms for IAs that do not fit under the umbrella of traditional IP protection. Current USAID and university policies are rather narrow and focus on dissemination, management, and commercialization of certain types of IPR, with a particular preference for patented innovations. These policies neither provide guidance on technologies that are not protected under IPR nor do they correspond to the unique attributes of agricultural technologies. As the study highlights, public institutions like CGIAR Centers mainly focus on IAs without seeking IPR due to the public good nature of agricultural investment. In addition, dissemination pathways for agricultural technology have particular characteristics – such as widely disbursed beneficiaries (farmers), small market size, and variation in commercial viability of crops – that must be taken into account.

- Some innovations developed with federal funding can be commercialized, but contractors and their partners face impediments such as filing and registration fees, capacity to monitor licensees and collection of royalties, and long lead time required to show viability of a product (particularly in the case of plant varieties). USAID should consider providing resources or additional funding mechanisms for innovations with commercial potential.

- ILs could benefit from enhanced coordination regarding dissemination and scaling pathways, including access to legal tools, so that there is a clear strategy/approach for transferring and disseminating technology. For example, tools could be developed on IP protection for agricultural IAs (including focus on PBR/PVP) and use of licensing agreements, which could be built into IL's strategy and specific dissemination needs.

- USAID could also adopt a dissemination and commercialization strategy framework through a technology transfer office that is made available to both in-house and external labs. This would enhance USAID's dissemination for federally-funded inventions, especially in furtherance of development goals.

- USAID could improve its current MEL framework focused on the three research thematic areas (Plant and Animal Improvement Research, Production Systems Research, and Social Science Research) to build out additional metrics that would assist in better management of IA/IP developed under USAID projects. This could include IL reporting on: (1)

technologies that have been protected under IPR, (2) licenses issued by IL host universities and partners for technologies developed with USAID funding, and (3) scaling pathways pursued by ILs for dissemination of innovations.

- Development of IA guidelines for GFSS projects based on good practices for agricultural IA/IP management would help guide USAID and its partners with regard to managing public agricultural innovations based on the goals of maximizing agricultural technology dissemination and effective management. While guidelines would need to be designed for USAID specifically, this study raises important questions for investment in agricultural technology more broadly, which could be expanded upon in future work.

- The NARES require capacity transfer to effectively disseminate IAs to farmers and marginalized communities, and legal tools could be further developed and leveraged to help them establish a reliable system for managing IAs and their dissemination. Engagement with NARES should also be emphasized across all scaling pathways.

5.3. Recommendations on Practices of Other USG Agencies, Donors, and International Partners

- Taking lessons from other USAID agencies, USAID could clarify its position on provisions in ADS 318 and the BDA that are unclear. This would provide greater predictability for contractors entering into funding agreements. Similar to some USG agencies, USAID could define the exceptional circumstances for modification of IP rights under a funding agreement. It could also clarify its march-in rights policy, which includes either taking title or assigning title to a third party. Finally, in cases where a university has declined to take title to an invention, USAID should clarify how it handles requests by an employee-inventor to take title.

- USDA and NIH policies address the possibility of allowing an employee-inventor to retain title to IP in cases in which a contractor waives title. The DOE and others clarify when modifications may be made to ownership rights under "exceptional circumstances." While USAID is unlikely to exercise march-in rights, it might consider furthering its goal of public good dissemination by setting out and negotiating conditions of IP ownership in a funding agreement, as allowed under the BDA.

- USAID could also clarify its position in the event the technologies are not protected or if a funding recipient does not meet the rights and restrictions set out under the BDA and ADS 318. For example, the DOE provides detailed guidelines for the creation of an IP management plan. USAID could consider adopting a similar policy, including establishment of IP management guidelines, such as the treatment of confidential information, a dissemination plan, and a commercialization plan.

- USDA provides guidance to its federally funded contractors to pursue IP protection for animal vaccines only if it enhances adoption of research outcomes (and not just income generation). This is useful guidance, as it discourages contractors from pursuing IP for

reasons other than achieving research goals. However, USDA only contemplates a commercial partner for technology transfer of such IP, which may not be sufficient for USAID's needs. Building on guidance from USDA, USAID could lay out its strategy to pursue IP protection or commercialization only if such protection is necessary to meet the public good objective of the agriculture IA.

- The DOC has a Technology Partnerships Office that helps both department employees and outside contractors with the development and commercialization of their inventions. The DOE has a similar office. Given the variety of IAs and scaling pathways available for agricultural technology, including the importance of licensing models for dissemination, USAID could look to these practices to inform its own policy on licensing to third parties. In this context, USAID could expand the ITR Hub to assist contractors with technology transfer.

- Other donors, particularly BMGF, have also adopted good practices from which USAID could learn. BMGF has developed an overall policy that requires grantees to ensure global access of outputs developed with BMGF funding. Further, BMGF's IP team negotiates various terms in relation to IP assets before funding is awarded. These include global access commitments, licensing, and PRIs. BMGF approach provides overall guidance to grantees on their IA/IP management, while also providing enough flexibility to customize specific terms on a case-by-case basis. USAID's approach is similar in that ADS 318 also guides negotiation of funding agreements on a case-by-case basis. However, these terms mostly pertain to traditional forms of IP, such as patents and trademarks, and do not adequately consider agricultural innovations, including those that are not covered under IPR, and their dissemination pathways (these are gaps in other agency and donor policies as well).

- USAID could draw lessons from its international partners, especially the CGIAR Centers that have developed IP policies specifically for agricultural innovations. The CGIAR IA Principles and their implementing guidelines are focused on global public access and use of CGIAR IAs, which are customized by individual CGIAR Centers based on their needs. Instruments like MTAs and licensing agreements, neither of which is based on IP, are used to disseminate and scale their IAs to maximize access. CGIAR Centers rarely pursue IP protection, as they want to keep their IAs in the public realm, and they also strongly discourage use of exclusive licenses. CGIAR is currently moving forward with the OneCGIAR initiative, and there is a working group focused on these issues that could provide additional insight.

CONLUSION AND AREAS FOR FURTHER INQUIRY

Partnerships and scaling pathways are major drivers for getting federally-funded innovations to the market and are even more central considerations than whether and how IAs are protected. Development of an IA/IP management policy is only the first step towards ensuring the broad dissemination of agricultural innovations. During consultations with stakeholders under this project, as well as legal and policy research, several areas arose that require further inquiry. First, because of the growing number of digital innovations produced with federally-funded research, USAID should consider expanding and clarifying its policy regarding data, particularly for AI-related products. Second, as a member of the FLC, USAID should consider addressing the dissemination of and IP rights related to agricultural innovations in additional FLC learning center modules. Third, a number of IAs expressed interest in shared tools on legal issues, such as IP protection and licensing. These could be developed and combined with FLC learning center modules. Fourth, because many of the projects surveyed included funding from both USAID and other donors, including BMGF, USAID should consider developing guidelines for co-funded projects. Finally, USAID could consider developing a better MEL System that tracks IAs produced by ILs. While all of these areas would require further research and analysis, they are presented briefly below.

6.1. Data Privacy and AI

Data rights and privacy are becoming increasingly important as more outputs from federally funded projects include large data sets and tools that depend upon AI. There are two ways to approach data in federally funded projects—one is the raw, quantitative data that must be shared under the USG's Open Data Policy, and the other is a data product, which can include tools developed with USAID funding, such as Penn State's Plant Village. Data products give rise to different questions that need to be addressed in USAID's IP/IA management policy. While a database itself may be copyrightable, the underlying data may include IP that belongs to others. USAID's data management guidelines do touch on this issue but leave it largely up to individual recipients to rely on their own IP policies.[252] While USAID and the BDA mention data ownership, they do not address issues related to data inputs that might be owned by local partners.[253] Even if data is not protected as IP, there are issues of privacy/access, ownership, and control of data which should also be addressed.[254] In preparation for collecting data or building an AI system, funding recipients must consider how to obtain informed consent of participants, who might claim the data and ethics on data collection and presentation, including when using AI. In addition, it is important to consider how data would be removed and returned if requested and whether the management plan is in

[252] "Open Data Policy Compliance Guide: A Practitioner's Guide to Interpreting and Complying with USAID's Open Data Policy," *Project Concern International*, 2017.

[253] *Id*.

[254] *Id.*; *see also* "The Thorny Issue of Data Ownership."

line with policies from different funders.[255] The USG has developed a "Blueprint for an AI Bill of Rights," which mentions data privacy, but this is still in an early stage of development. It uses broad terms of protection and suggests that developers should seek permission for data use as well as agency over the means of collection and use.[256] The existing framework deals with the collection and use of personal identifiable information (PII), rather than ownership of underlying data. AI raises even more complicated legal and ethical questions, including monitoring, management, and contingency plans, which USAID and other USG policies do not address. It is important to understand data rights for contractors developing software or technical databases, because the government has different licensing rights depending on when and with what funding that technology was developed.[257] It is also critical to understand the rights of those in developing economies who provide data for these tools but are not able to exercise rights or, in some cases, freely access the tools their data helped build.

6.2. Agricultural IA Learning Modules

As mentioned in Section 4, the FLC offers free educational training modules for certain aspects of IP and technology transfer. However, this is geared primarily toward government-owned technology as well as traditional pathways for IP protection. Because these training modules are readily available and user-friendly, USAID should consider proposing that the FLC include modules that cover innovations developed by external contractors as well. In order to cover different strategies of dissemination and technology transfer, modules could be added on pathways for agricultural innovation dissemination, and licensing strategies for publicly funded innovations. Other modules could include issues relating to the topics covered by the Interagency Working Group on Competition and Intellectual Property on Seeds, including IP rights in plant-related inventions (including PVPs), the appropriate use of licenses for plant-related inventions, the enforcement and use of licenses, and the fair-market exercise of IP rights in plant-related inventions.[258] Many of these modules could be developed by expanding on the issues covered in this report.

6.3. Development of Legal Tools for ILs and Partners

Related to the learning materials described above, legal tools and capacity transfer programs could be developed for the IAs and their partners. These could include tools on intellectual property protection and licensing and capacity transfer for ILs and their partners, which must address a

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[255] Kim Murphy et al., "Open Data Policy Compliance Guide: A Practitioner's Guide to Interpreting and Complying with USAID's Open Data Policy," *Project Concern International*, 2017; *see* Sophie Goossens et al., "The Thorney Issue of Data Ownership," *ReedSmith*, February 5, 2024; *see e.g.* ECOWAS Supplementary Act, Supplementary Act A/SA.1/01/10 on Personal Data Protection within ECOWAS, Chapter IV. Article 19 (3) a-c and Article 20(1-3). Abuja, February 16, 2010; *see also* Sean McDonald, "Ebola: A Big Data Disaster: Privacy, Property, and the Law of Disaster Experimentation," *Centre for Internet and Society*, March 2016.

[256] "Blueprint For an AI Bill Of Rights: Making Automated Systems Work for The American People," White House 6, October 2022.

[257] ADS 318.3.2.2.

[258] "Promoting Fair Competition and Innovation in Seeds and Other Agricultural Input Industries," USDA,accessed August 23, 2024.

number of legal questions but which lack specialized legal support in areas related to agricultural innovation. Capacity development could also be focused on enhancing the ability of the ILs to engage in policy and regulatory issues. Several of the ILs noted an interest in capacity transfer related to legal and regulatory issues, both with respect to their own operations and regarding their engagement in developing economy markets. Although a few ILs work on policy issues, legal and regulatory issues seem to be a gap that could be pursued through an IL or under a separate initiative designed for the existing ILs.

6.4. Harmonizing Legal Guidelines for Cofinanced Projects

Many agricultural research projects are co-financed by multiple donors, such as USAID, BMGF, bilateral agencies, and other multilateral organizations. In most cases, the implementing institutions manage separate contracts with each donor, which adds layers of administrative complexity. While co-financing is widely praised for its ability to mobilize diverse resources and enhance donor coordination, it also introduces significant challenges for project implementers, particularly regarding the attribution of donor contributions to specific project outputs.[259] The lack of a unified approach among donors can result in inefficiencies and increased operational burdens.

One of the critical challenges is the absence of harmonized guidelines for managing donor contributions and resulting IAs. Without such guidelines, conflicts frequently arise over the legal frameworks governing technology transfer, as each donor may have different stipulations and requirements. In these situations, implementing institutions often default to the most restrictive policies, which usually take precedence, thereby limiting flexibility and innovation.[260] This restrictive approach can further complicate the dissemination of agricultural technologies, which often require tailored strategies to effectively manage, disseminate, and scale innovations to reach their intended end users. The fragmented nature of guidelines from various funders exacerbates these challenges, particularly in the context of public good research outputs that are meant to benefit broad user bases, including smallholder farmers and local communities. The variability in donor requirements can lead to inconsistent practices across projects, making it difficult to ensure that agricultural technologies are disseminated and scaled in a way that is both efficient and aligned with local needs and conditions.[261] This inconsistency can undermine the overall impact of agricultural research, reducing the effectiveness of technology transfer and adoption.

This report is timely in highlighting these key challenges related to the management of IA in agricultural research institutions. USAID, given its significant role in global agricultural research funding, could capitalize on the momentum generated by this report to convene strategic meetings

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[259] "Donor Coordination in Agricultural Research," OECD Publishing, 2019; D.J. Spielman and K. Von Grebmer, "Public-Private Partnerships in Agricultural Research: An Analysis of Challenges and Opportunities," *International Food Policy Research Institute (IFPRI)*, 2020.

[260] R. Tripp, "The Impact of Agricultural Research in Developing Countries: Lessons from CGIAR Research" World Development 31, no. 5, (2003): 713-32.

[261] A. Hall "Challenges in Strengthening Agricultural Innovation Systems: Learning from the Agricultural Research and Extension System in India," Agricultural Systems 94, no. 2 (2007):174-86.; CGIAR, "Managing Intellectual Assets for Agricultural Development: Guidelines and Best Practices," CGIAR Consortium, 2021.

with major donors. The goal of these meetings would be to design or establish general guidelines to streamline the management of public good IAs in agriculture. By fostering a more harmonized framework, not only would conflicts over legal frameworks for technology transfer be reduced, but the ability of local partners – such as NARES and other research institutions – to disseminate agricultural technologies effectively would also be enhanced. Such a framework would ensure that these efforts are better aligned with both practical needs on the ground and the diverse guidelines and policies of donors, ultimately leading to more sustainable and impactful agricultural development.[262]

6.5. Development of MEL System that Tracks IAs produced by ILs

USAID currently uses the PIRS within the GFSS to provide a structured framework for tracking the development and progression of new or significantly improved technologies, practices, and approaches. Despite its strengths, stakeholder consultations have identified certain limitations within this MEL system, particularly when it comes to capturing and tracking IAs. The current framework does not adequately address the complexities associated with managing IAs once they have been developed within the ILs and subsequently transitioned to external partners or stakeholders. As a result, there is a significant gap in the system: no concerted or systematic effort exists to monitor the management and utilization of IAs after they leave the ILs. This gap means that USAID lacks a formal mechanism to track and document the successes and challenges that may arise downstream during the critical phases of technology transfer, dissemination, and scaling.

The absence of such a mechanism can have important implications. As highlighted in this report, the legal frameworks governing the management of agricultural IAs play a crucial role in determining the pathways through which these technologies are scaled and their overall impact. Without a robust system in place to monitor how IAs are managed post-IL, USAID and its partners may miss opportunities to identify best practices, address emerging challenges, and make informed adjustments that could enhance the effectiveness of technology dissemination and adoption. Furthermore, the ability to track IAs beyond their initial development stages would provide valuable insights into the long-term outcomes of these innovations and their contributions to the broader goals of food security and agricultural development.

Given these considerations, USAID could explore ways to modify and enhance the existing MEL systems to include specific mechanisms for tracking the management and utilization of IAs for each innovation. This could involve developing new indicators (including those that track with legal considerations), integrating IA management into the existing phases of technology development, and creating dedicated tracking tools that follow IAs throughout their lifecycle. By doing so, USAID would be better positioned to ensure that the innovations it supports are effectively managed and scaled, ultimately leading to greater impact and sustainability in the agricultural sector.

[262] IFPRI, "Donor-Funded Agricultural Research: Trends, Impacts, and Challenges," International Food Policy Research Institute (IFPRI), 2022.

Annexes

Annex 1: List of Stakeholders Consulted

	Name and Position	Organization	Date of Interview
Innovation Labs			
1.	Dr. Thumbi Mwangi, *Lab Director* Dr. Nicholas Svitek, *CGIAR - Senior Scientist*	Feed the Future Innovation Lab for Animal Health - Washington State University	Feb. 1, 2024
2.	Stephen Kresovich, *Lab Director*	Feed the Future Innovation Lab for Crop Improvement - Cornell University	Feb. 7, 2024
3.	David Hughes, *IL Director*	Feed the Future Innovation Lab for Current & Emerging Threats to Crops - The Pennsylvania State University	Jan. 10, 2024
4.	David Tschirley, *IL Director*	Feed the Future Innovation Lab for Food Security Policy Research, Capacity and Influence - Michigan State University	Dec. 21, 2023
5.	Patrick Webb, *IL Director*	Feed the Future Innovation Lab for Food Systems for Nutrition - Tufts University	Dec. 19, 2023
6.	Dr. Mark Lawrence, *Lab Director*	Feed the Future Innovation Lab for Fish - Mississippi State University	Feb. 27, 2024
7.	Archie Jarman, *Associate Director from the Innovation Lab*	Feed the Future Innovation Lab for Horticulture - University of California, Davis	Jan. 11, 2024
8.	David DeYoung, *Program Manager* Joseph Huesing, *Patent Scientist - USAID Contractor*	Feed the Future Innovation Lab for Legume Systems Research - Michigan State University	Dec. 22, 2023
9.	Dave Hoisington, *Innovation Lab Director* Jamie Rhoads, *Innovation Lab Assistant Director*	Feed the Future Innovation Lab for Peanut - University of Georgia	Dec 19, 2023
10.	Dr. Peter D. Goldsmith, *Director & Principal Investigator* Brian Diers, *Deputy Director*	Feed the Future Innovation Lab for Soybean Value Chain Research - University of Illinois	Jan. 26, 2024

11.	Dieudonne Baributsa *Director, PICS Program*	Purdue Improved Crop Storage (PICS) Program, Purdue University	June 18, 2024
12.	Devon Jenkins *Program Manager*	Feed the Future Innovation Lab for Crop Improvement - Cornell University	August 2, 2024
NARES			
13.	Patriciah Ngutu	Kenya Agricultural and Livestock Research Organization (KARLO)	June 27, 2024
14.	Joseph Mbihayeimaana, *Senior IP Officer*	National Agricultural Research Organization (NARO) - Uganda	June 21, 2024
15.	Petronella Chaminuka, *Head of Economic Analysis Unit* Cynthia Motsi, *Senior Manager: Intellectual Property and Commercialization*	Agricultural Research Council, South Africa	July 2, 2024
16.			
CGIAR Centers			
17.	Nicholas Davis James *Program Manager, Maize* Christopher Ochieng *Partnerships and Seed Systems Lead, AVISA*	International Maize and Wheat Improvement Center (CIMMYT)	April 17, 2024
18.	Dean Mungaani *IITA Product Manager for Grain Crops*	International Institute of Tropical Agriculture (IITA)	March 14, 2024
19.	Ian Barker, *Senior Director, Strategy, Delivery and Scaling*	Consultative Group on International Agricultural Research (CGIAR)	May 2, 2024
20.	Michael Halewood *Generic Resources and Seed Systems Policies Team Leader*	International Center for Tropical Agriculture (CIAT)	May 9, 2024
21.	Discussion in OneCGIAR Licensing Group (Katrin Kuhlmann member of group)	OneCGIAR	Ongoing
Other Donors			
22.	Lauren Good *Senior Program Officer*	Bill and Melinda Gates Foundation	December 1, 2023

Annex 2: Guiding Questions for Stakeholder Consultations

I. INNOVATION LABS

A. INITIAL QUESTIONS FOR USAID & INNOVATION LABS – RELATIONSHIP BETWEEN INNOVATION LABS & USAID

1. Are Innovation Lab established as independent legal entities apart from the Feed the Future (FtF) university partners?
2. How is the relationship between the Innovation Labs and USAID structured? Is there an **agreement** between the Innovation Lab and USAID, or is the agreement done between the university that houses the Innovation Lab and USAID? Could we obtain a copy of the agreements, or their clauses related to technology and IP?
3. Do the Innovation Labs have IP policies, or are they governed by the university IP policies?
4. Do university or Innovation Lab IP policies or management frameworks, include clauses on how to manage technology arising from partnerships or financial support provided by the U.S. federal government?
5. If the Innovation Labs receive funding from multiple sources, including but not limited to U.S. government sources, how does that impact IP management?
6. Does the relationship between USAID and the Innovation Labs also cover the common pathways for dissemination of innovation to the end users? Could you walk us through these pathways?

B. QUESTIONS REGARDING TECHNOLOGY DEVELOPMENT, INTELLECTUAL PROPERTY MANAGEMENT, AND TECHNOLOGY DISSEMINATION

Technology Development

1. Is all technology developed by the Innovation Lab protected as IP? How do you determine whether the technology should be protected as IP?
2. If the technology produced by the Innovation Lab is protected as IP, what kind of IP is created? Please provide examples.
    a. Copyrights
    b. Patents
    c. Trade secrets
    d. Trademarks
    e. Other _____
3. In what jurisdiction is IP obtained? United States? Other countries? How are jurisdictional issues considered with respect to globally disseminated IP?
4. What factors go into determining the IP form and jurisdictional coverage?

5. Are there special considerations (and particular approaches) for certain kinds of technology, e.g., biotechnology?
6. Who performs the Research & Development (R&D) activities and develops the inventions in your Innovation Lab?
    a. The Innovation Lab's own employees
    b. Staff, students, or professors at partner university
    c. An external third-party contracted by the Innovation Lab
    d. If Other, please specify: _____
7. Who generally owns the rights to an invention created in your Innovation Lab?
    a. The partnering university
    b. The Innovation Lab
    c. The inventor
    d. Other: _____
8. Are you aware of the Bayh-Dole Act? (The Bayh-Dole Act is a federal law that enables universities, nonprofit organizations, and small businesses to own, patent, and commercialize inventions created with federal funding.)
    a. Yes
    b. No

Technology Dissemination

9. How do the IP policies and practices in use by the Innovation Lab relate to technology transfer?
10. What are the common approaches and pathways for dissemination of technology developed by the Innovation Labs (NB: This and other questions will be relevant for CGIAR)?
11. Is the technology developed by the Innovation Lab licensed for dissemination? Are the licenses based on IP?
12. If licenses are used, how does the Innovation Lab's internal policy regulate exclusive and non-exclusive licenses?
13. How does the Innovation Lab work with other partners (CGIAR, NARES, EGS aggregators, etc.)? Are these relationships governed by agreements or contracts?
14. If there is an agreement between the Innovation Lab and USAID, does it regulate the type of licenses your Innovation Lab may grant? (type of license examples: exclusive license, non-exclusive license)
15. Overall, which approaches and strategies have worked well, and which have not? (Please provide specific examples where available).

II. CGIAR CENTERS

A. QUESTIONS REGARDING TECHNOLOGY DEVELOPMENT, INTELLECTUAL ASSET MANAGEMENT, AND TECHNOLOGY DISSEMINATION

Technology Development

1. Based on the CGIAR Principles on the Management of Intellectual Assets, could you elaborate on how your CGIAR Center approaches protection of Intellectual Property (IP)?
2. How does the IP policy for your individual CGIAR Center address this issue? Does it differ from the CGIAR Principles?
3. If the Center's assets may be protected as IP, how do you determine whether the technology should be protected as IP? Is exploitation by a third party an issue?
4. Is your CGIAR Center currently protecting any IP? If so, what kind of IP is created? Please provide examples.
    a. Copyrights
    b. Patents
    a. Trade secrets
    b. Trademarks
    c. Other _____
5. If you do obtain IP protection, in which jurisdiction is IP obtained? How are jurisdictional issues considered with respect to globally disseminated IP?
6. Who generally owns the rights to technology developed by the CGIAR Center?
    a. The partnering university
    b. The CGIAR Center
    c. The inventor
    d. Other: _____

Technology Dissemination

7. Given the goals of further improvement of the IA and enhancing the scale and scope of impact on target beneficiaries, what is your strategy/ policy/practice related to technology/IA/IP transfer or dissemination.?
8. How does your CGIAR center approach different kinds of licenses for intellectual property (exclusive, non-exclusive, semi-exclusive)?
9. How does your CGIAR Center work with other partners (NARES, EGS aggregators, seed companies, etc.)? Among these partners, how does your CGIAR Center determine which partner is best suited to dissemination? Are any of these partners prioritized over others, and why?
10. Are these relationships governed by agreements or contracts? What form do they take?

11. Does your IA/IP policy allow inventors to assign or transfer inventions to third parties? If so, are there any restrictions tied to it?
12. Overall, which approaches and strategies have worked well, and which have not? (Please provide specific examples where available).

Additional Questions

13. How is the relationship between the CGIAR center and USAID structured? What does it cover? Could we obtain a copy of the agreements, or their causes related to IA, technology, and IP?
14. If the CGIAR Center receives funding from multiple sources, including but not limited to U.S. government sources, how does that impact IP management?
15. If you have an IP policy, could you kindly share it with us?
16. When you collaborate/partner with USAID for specific programs/projects that involve the development of an invention through federal funding from USAID, how do you **manage** your intellectual property?
17. Where the CGIAR Center transfers or disseminates a technology that is subject to third party IP rights, how does it protect those rights?

a. NARES

1. What is the landscape of agricultural technology being disseminated?
2. What is the arrangement with other partners, donors, maybe the CGIAR centers? Are there any gaps or issues in these arrangements? What has been most successful in ensuring that the technology gets out to farmers?
3. Does the NARES have any connections to the universities or national research institutions?
4. What kind of IP/IA is generated and protected by NARES? What is the legal IP basis for these arrangements?
5. What licensing model is being use by the NARES? Are there are any examples of where you use patents or utility models for a particular product.
6. What is the regional approach to licensing? Do you have to compete with private sector companies?
7. Do you have any interactions with ILs?

Annex 3: Case Study Survey for Innovation Labs

I. Purpose of Survey

The purpose of this survey is to further collect the specific information about a specific intellectual asset (technology/invention/product) from your innovation lab. We would like to get more details on the current or proposed institutional frameworks for scaling or disseminating the technology to target audiences.

II. Survey Questions

Below is the list of questions take from the survey sent to selected ILs.

1. Please indicate the name of your innovation lab:
2. Please indicate the email of person who is filling this survey:
3. Please specify one intellectual asset (technology/invention/product) from your innovation lab that you would like to highlight as a case study. Give a brief description of the technology/invention/product (feel free to add URL of website where we can get more details).
4. Please list all partners/collaborators involved in the research stage of the specified intellectual asset. What is/was the form of your partnership/collaboration?
5. Please list all partners/collaborators involved in the field trial/experimental stage of the specified intellectual asset. What is/was the form of your partnership/collaboration?
6. Please list all partners/collaborators involved in the commercialization/distribution/manufacturing stage of the specified intellectual asset. What is/was the form of your partnership/collaboration?
7. Does the management of the specified intellectual asset fit any categories listed below (check all that applies)
    - Patent
    - Trademark
    - License (exclusive, semi-exclusive or non-exclusive)
    - Copyright
    - Trade secret
    - Paywall for access
    - Contracts
    - Other:
8. Could you explain how the abovementioned intellectual asset is managed?
9. In what way did considerations about protecting the intellectual assets impact the ability to disseminate or scale up adoption?
10. Is there any information about the management of Intellectual assets that you would like to share with the research team?