

**atTC** Aflasafe Technology Transfer and  
aflasafe Commercialization (ATTC)

## Structuring the Business Relationship



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## Acronym List

ASU	Arizona State University
ATTC	Aflasafe Technology Transfer and Commercialization
AzTE	Arizona Technology Enterprises
BIP	Business Incubation Platform
IA	Intellectual Assets
IITA	International Institute of Tropical Agriculture
IP	Intellectual property
M&D	Manufacturing and distribution
P4D	Partnership for Delivery
TTLA	Technology Transfer Licensing Agreement
USAID	United States Agency for International Development
WIPO	World Intellectual Property Organization



## I. Introduction

The International Institute of Tropical Agriculture (IITA) has developed a unique solution, Aflasafe, to address aflatoxin contamination in major staple cereal crops in Africa. Through more than a decade-and-a-half of research and development, IITA and its partners have developed this product by identifying friendly fungi that are highly effective at reducing aflatoxin levels, then testing them in farmers' fields. This testing has helped IITA create the best composition of Aflasafe for each country while providing data needed for the registration and regulatory process. The widespread application of Aflasafe in aflatoxin-affected areas has the potential to significantly increase quantities of aflatoxin-safe maize, sorghum, and groundnuts, and significantly reduce health effects of aflatoxin, including stunting in children and liver cancer. Through Aflasafe, IITA seeks to contribute not only to improving food safety but also increasing the income of smallholder farmers.

To achieve these goals, IITA must widely deliver Aflasafe to agricultural value chain actors. However, developing an extensive production, distribution, and marketing operation throughout Africa to commercialize Aflasafe is not in line with the CGIAR Intellectual Assets (IA) Principles or the mandate of IITA as a non-profit research institution. After considering various options for manufacturing and distribution, IITA decided to pursue Aflasafe commercialization, led by the private sector and supported by the public sector, to turn this scientific innovation into a commercial product.

**Exhibit 1. Science to Scale Commercialization**



To facilitate the commercialization process, IITA received a grant from the Bill & Melinda Gates Foundation and the United States Agency for International Development (USAID) for implementation of a five-year initiative entitled Aflasafe Technology Transfer and Commercialization (ATTC), which is managed by IITA through the Business Incubation Platform (BIP). IITA hired Chemonics International, Inc. and Dalberg Advisors to support the implementation of ATTC. Aflasafe commercialization began in 2016 and has since expanded. Aflasafe is currently commercially registered and available in seven countries: Burkina Faso, The Gambia, Ghana, Kenya, Nigeria, Senegal, and Tanzania. As of October 2019, 12 more countries across Africa are at different stages in the pipeline for eventual Aflasafe commercialization: Benin, Burundi, Cameroon, the Democratic Republic of the Congo, Ethiopia,

Malawi, Mali, Mozambique, Rwanda, Zambia, Uganda, and Zimbabwe. In each country, ATTC researches the potential for commercialization, identifies and attracts potential investors, transfers the Aflasafe technology to an investor, and supports the manufacturing, distribution, and marketing efforts in such a way that the Aflasafe product will be available locally in an economically viable, sustainable, and independent way for many years to come.

To enable the continued commercialization of Aflasafe and potentially support IITA or other CGIAR institutions in commercializing other products in the future, IITA, Chemonics, and Dalberg, under ATTC, have created four guides which outline the core processes of commercialization, i.e., how to take scientific research products to market. These guides include Market Assessment and Strategy Development, Investor Selection, Structuring the Business Relationship, and Implementation of the Business Development Strategy. A summary of the four guides is presented below in the order of the commercialization process.

1. **Market Assessment and Strategy Development:** This guide describes the process that the ATTC initiative created for developing a commercialization strategy for Aflasafe, demonstrating how it can become a marketable farm input for sale in a specific country. The guide introduces the concept of commercialization and how it relates to IITA's activities, outlines the desired outcomes of the market assessment and strategy development process, and suggests steps to be taken to develop a high-quality document featuring findings and conclusions backed by data—including the country context, market analysis, forecasts of Aflasafe uptake, a review of manufacturing potential, and identification of potential investors. The process should take approximately 4-6 months in total—if assigned to a dedicated team with no unforeseen delays. Once the commercialization strategy is in place, there should be a clear understanding of how to commercialize Aflasafe in the country by prioritizing core market segments that are sensitive to aflatoxin and thus more likely to adopt Aflasafe. The strategy also informs the capacities and expertise needed by an investor to undertake manufacturing, marketing, and distribution.
2. **Investor Selection:** This guide discusses the ATTC initiative's recommended process for sourcing potential partners, analyzing investor options, and ultimately selecting the investor(s) in a specific country with the best potential for success in the manufacturing, marketing, and distribution of Aflasafe. The initial ideas for partner identification will be generated during the strategy development process, with multiple submissions from partners and reviews by IITA, culminating in a final selection by an advisory board based on presentations and recommendations. The selection process should take approximately 4-6 months if completed efficiently and without delays.
3. **Structuring the Business Relationship:** This guide shares the ATTC initiative's experiences navigating CGIAR policies and practices and partner motivations to structure a business relationship with the private sector investor selected to become the manufacturing and distribution (M&D) partner for Aflasafe. It provides guidance to a non-legal audience on crafting the legal document needed for the transfer of the Aflasafe technology: a Technology Transfer Licensing Agreement (TTLA). The guide covers why this type of license agreement was selected by IITA as the core legal document for the process, provides questions to consider when tailoring the TTLA template, and offers insights into negotiations with M&D partners to date. The TTLA process can take 1-2 months, depending on the level of negotiation required.

- 4. Implementation of the Business Development Strategy:** This guide captures ATTC's experiences working with the selected M&D partner to hand over valuable business knowledge developed throughout this process. This guide provides background information, lessons learned, and the recommended process for developing the key deliverables, including consumer profiles of potential buyers, a business case for the marketing of Aflasafe, and a handover memo for the selected partner. The guide addresses each of the key sections of these documents and shows their importance in facilitating the marketing and sales of Aflasafe to potential buyers. The development, consolidation, and handover of this information should take a total of 3-4 months using the standardized templates and tools.

Please note that these guides are not exhaustive manuals, and thus should not be considered a complete list of steps to take. Also keep in mind that the approaches and guidance should be modified and contextualized for each target market and adjusted for changing dynamics. The guides have been designed with Aflasafe in mind but may be a starting point to adapt for other IITA or CGIAR products. As such, we have included considerations for products beyond Aflasafe throughout the guides.

This guide is focused on the official transfer of a scientific product to a private sector partner within the commercialization process.

## II. Overview of Structuring the Business Relationship

### What is a Technology Transfer and Licensing Agreement?

A Technology Transfer and Licensing Agreement, or TTLA, is a legal document, outlining the terms and conditions for how one organization is licensed to use a patented technology or intellectual property (IP) developed by another organization. According to the [World Intellectual Property Organization](#) (WIPO), a TTLA is an agreement whereby an owner of a technological intellectual property (the licensor) authorizes another party (the licensee) to use the technology under certain agreed terms and conditions. The TTLA is the selected business relationship management agreement for Aflasafe, explained further below in the section, “How is a TTLA applicable to Aflasafe?”



In the majority of technology transfer cases, TTLAs are agreements that enable a private company to access a patented innovation developed by a public institution, such as a university or a research organization. The license allows the public institution (licensor) to reinvest fees or royalties received from the transfer into future research products and innovations while also ensuring their product is successfully scaled and accessible; at the same time, the licensee leverages their marketing knowledge and business acumen to reap financial benefits from the commercialized product of research. In some cases, a TTLA can be between two private sector companies

when the licensor (holder of IP through a registered patent, purchase from initial innovator, or non-exclusive license) does not or cannot invest in the assets required to enter a new market. In these cases, the licensor instead licenses elements of their technology to a private sector licensee with existing infrastructure and/or market presence with the willingness to take on the operational risks in a previously untapped market. For the purposes of this guide and any future work at IITA, we will focus on the transfer of technology from a public sector institution (IITA, a CGIAR institution) to private sector companies or partners.

These agreements are the preferred mechanism for transferring patented technologies in a fair and reasonable manner that will ensure the same high-quality standards when scaling up or replicating the product or innovation. A TTLA outlines the roles, responsibilities, and expectations for both parties to ensure quality standards are maintained, for example, continued access to the public institution’s experts to help the private sector partner achieve their business goals, and/or monitoring and evaluation by the public institution, including corrective measures, as needed.

### How is a TTLA Applicable to Aflasafe?

The goal of the TTLA between IITA and a private company is to grant non-transferable and non-sublicensable rights for manufacturing, distribution, and sale of the Aflasafe product. Per the [CGIAR Principles on the Management of Intellectual Assets](#)<sup>1</sup> (See box, click hyperlink, or follow website link in footnote below), the results of CGIAR

**CGIAR Principles on the Management of Intellectual Assets**

CGIAR regards the results of its research and development activities as international public goods and is committed to their widespread diffusion and use to achieve the maximum possible access, scale, scope of impact, and sharing of benefits to advantage the poor—especially farmers—in developing countries.

<sup>1</sup> <https://cgspace.cgiar.org/bitstream/handle/10947/4486/CGIAR%20IA%20Principles.pdf?sequence=5>

research and development are considered international public goods. IITA, with support from partners and donor funds, developed the Aflasafe technology—an all-natural, easy-to-use yet very effective product—to combat aflatoxins across Africa. However, IITA cannot meet the entire continent’s addressable demand for Aflasafe within its current resources, nor is mass production or direct distribution part of its vision or mandate. Direct production and sale is also not legally possible for IITA as a non-profit institution; per the CGIAR Intellectual Assets (IA) principles, any revenue (slight fees collected beyond actual costs and reasonable processing fees) shall be used by the Center to support the CGIAR vision. Instead, as outlined in the IA principles, IITA may grant limited exclusivity for the commercialization of the respective IA when conditions are met (Section 6.2 Limited Exclusivity Agreements of the CGIAR Principles; see IITA database/toolkit). In the case of Aflasafe, IITA seeks to partner with private companies to both manufacture and distribute the product. As IITA continues to examine various partnering options in different countries and contexts, details of the TTLAs used will evolve and change. Regardless, the primary goal remains the same: transfer the know-how to produce Aflasafe, maintaining high product quality standards and assuring the product is available at a reasonable price and accessible to most of Africa.

### **Why should Aflasafe be licensed?**

***Private sector advantages.*** As the private sector permeates the development landscape and public funds become scarcer, IITA and other CGIAR institutions will continue to explore how to balance their primary objective of developing goods that benefit society as a whole, while also ensuring there are viable, practical, and sustainable means to get those goods to the intended beneficiaries. Available public funds are primarily used within IITA to support scientists in the development of a product and as proof of efficiency. By then transferring the necessary proof and protocols to a private sector partner or national government and taking a business approach to mapping out and using distribution channels, IITA can leverage market forces for Aflasafe uptake. A market-driven approach to Aflasafe distribution focuses first on the target segments willing to pay for this additive input, which then allows the partner to reinvest and expand distribution channels and marketing efforts to second- and third-tier markets. Getting the goods to the last mile, an original and continual goal of IITA, is only possible by working through and with the private sector to create a cycle of financial support to regenerate and sustain the operations. This simultaneously allows the research institution to maintain its focus on high-quality products and research versus chasing a profit margin. The alternative to a partnership with the private sector is to continue to invest public funds into what should be a market-driven business venture. This is not a viable option. A further analysis of other commercialization partnership options—and why commercialization through a TTLA was ultimately selected for Aflasafe—is included in the Commercialization Partnership Options for Aflasafe which can be found in the IITA database/toolkit.

***New strategy to accomplish IITA’s mission.*** ATTC is the first attempt to commercialize technologies developed by IITA. This is in line with the creation of the Partnership for Delivery (P4D) Directorate and the Business Incubation Platform (BIP) within that Directorate. The IITA-P4D Directorate was established in October 2016 to coordinate the dissemination of demand-driven technologies and knowledge at scale that will stimulate and facilitate agricultural transformation and prosperity in a sustainable manner. Historically, it has been a challenge to get scientific breakthroughs into public hands at a mass scale. Instead of developing

transformative technologies that sit on shelves or are only available to a small few, IITA, through ATTC, has embarked on a new journey, a partnership with the private sector.

**Licensing is a growing trend** (see box). The transition from science to use and consumption has been a challenge impacting many public research institutions. Universities and other public innovation spaces have embraced the TTLA process as a fair and transparent approach to achieving the common goal of getting products into the hands of users to effect positive change. The financial returns from TTLAs through licenses or royalties can also help fund further research and university programs, especially when public funding in education is volatile. Likewise, the use of TTLAs is new for CGIAR centers since it further expands upon their traditional mandate to develop international public goods. However, as noted in the 2018 CGIAR Intellectual Assets Management Report, the use of Limited Exclusivity Agreements by CGIAR centers, once an exception, is now a growing trend—the International Maize and Wheat Improvement Center has seen an unprecedented 68 limited exclusivity agreements compared to the two limited exclusivity agreements signed by IITA, both with Aflasafe M&D partners.

**Licensing technologies, a growing revenue source for universities**

According to an annual [AUTM survey](#), approximately \$1.3 trillion in gross licensing revenue was reported by U.S. universities in 2017. Rankings in licensing, commercialization, and start-up indexes, like the one [developed by the Milken Institute](#), can also contribute to a university's prestige.

**Quality control.** IITA currently owns the IP for Aflasafe and will remain the owner for the foreseeable future. Overall, the IP is four families of atoxigenic *Aspergillus flavus* fungi, known as the mother cultures, to produce the active ingredients of each Aflasafe product. The next step is the process of cleaning, roasting, and coating the sorghum with the inoculum and blue dye to produce Aflasafe.<sup>2</sup> The final step in producing Aflasafe involves product quality checks and packaging. The knowledge of the production process is transferred to the private sector partner through the licensing, while the mother cultures and the registered product remain the property of IITA. IITA is also open to exploring the possibility of transferring the mother culture (local government regulations permitting) to partner companies with established high-quality laboratories with high-skilled personnel on a case-by-case basis.

How the product is registered may vary from country to country, but IITA's reputation will forever be associated with Aflasafe and, as such, IITA has a vested interest in ensuring the integrity of the mother culture is maintained and safeguarded. Furthermore, in many countries, the preference mandated by the host government's standards and controls authority is for the mother culture to remain the responsibility of IITA. A biological agent, the mother culture is the active ingredient for Aflasafe. This breakthrough technology is the main element of Aflasafe and the core intellectual property enabling Aflasafe to be successful. It remains the responsibility of IITA to ensure the quality of the mother culture, including but not limited to adjusting the culture to the specific ecological context and strains, or adjusting over time, if and as needed.

While the manufacturing process is explained within manuals, workshop layouts, and equipment specifications, the TTLA assumes all information and knowledge is transferred except for the mother culture. IITA produces and maintains the mother culture and only avails it to the licensed private sector partner for multiplication and use in the making of Aflasafe.

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<sup>2</sup> As IITA is a research and learning institution, the technology may continue to evolve, as may the relationships and responsibilities within each stage of the process. What is described above is the current process as of 2019.

## What is the best way to navigate the CGIAR Principles and Practices on Management of Intellectual Assets?

Thoughtful guidance and guiding principles can help ensure that innovations can serve practical purposes while also serving as catalysts for future innovations. This section outlines specific references within the CGIAR IA principles, to help future innovators navigate the framework that enables a partnership with the private sector.

**Exclusivity terms.** Exclusivity is referenced within Principle 6. Maximizing Global Accessibility and Impact, and is explicitly defined in Section 6.2. Limited Exclusivity Agreements, without reference to any term limits. Prior to ATTC, the general practice for an exclusivity license was a three-year term. ATTC, based on breakeven calculations, an initial commercialization strategy, and prospective partners, requested, received approval for, and implemented five-year terms. Realizing the extensive resource investment required, many M&D partners have requested 10-year terms; however, since they are still relatively unknown to IITA, 10-year terms have not and will not be considered in the foreseeable future. At the same time, assuming the relationship continues to be productive for both parties, the agreement can easily be renewed and extended before the end of the first term. The consideration of an extension as exclusive or non-exclusive depends on a number of factors, including market responsiveness and the potential need for additional incubation support of one partner as they continue to grow the market response to this new product category.

**CGIAR Monitoring of IP licenses.** Each CGIAR Center is required to report how many licenses are valid, total duration of the license, and the stage or year of each relationship; in the case of IITA, the organization has to provide a rationale each year for any new exclusivity agreement, its duration, and how the existing relationships are being managed. One of the most common questions or concerns that comes up every year regards the safeguarding of public interests, both to “ensure no harm” and to see that innovations are focused on mitigating some of the world’s most complex agricultural issues. There is explicit intention within the CGIAR IA principles to protect the public interest (see box).

### CGIAR Principles protect public interest

In line with IITA’s CGIAR IA principles, the product shall remain available in all countries for non-commercial research by public sector organizations in furtherance of CGIAR vision (Research Exemption) and in the event of a national or regional food security emergency (Emergency Exemption).

**Ethical, fair, and transparent negotiations.** As a public institution, CGIAR centers are held to high standards for all business interactions. While some could consider IITA to have the upper hand in negotiating the TTLA, as it holds the technology patent and know-how, IITA knows that the product will not get to the last mile of the public without a private sector M&D partner and does not seek to control all decisions or issue ultimatums. IITA’s goal is not to maximize profits or get the best deal but to ensure their technology and innovations can reach farmers country-wide. The TTLA negotiation is a small but important part of a longer-term relationship. In order to maintain a productive working relationship, IITA approaches all conversations with fairness, respect, and transparency. ATTC proactively shares the CGIAR IA Principles as foundational information regarding its position on exclusive licenses and approaches to working with the private sector M&D partner who will profit from IITA’s extensive research, development, and testing of innovations.

**Pricing considerations.** If there were other competitive products that could deliver anything similar to Aflasafe, then the market would self-regulate supply and demand with companies competing for business through price, quality, and access. In this case, however, IITA is responsible for monitoring the quality of the product, which, in terms of standards and consistency, should not be allowed to waver. In theory, access and price could differ, if there is more than one manufacturing and/or distribution partner in a market. However, when an exclusive license is granted in a market there is no competition, and thus no market-driven price regulation beyond a consumer's willingness to pay. Staying true to IITA's primary interest in making this product available to all, the licensing agreement contains pricing considerations in Clause 3.2. General Obligations of the M&D partner. Regulating the price ensures it is an accessible product, while also enabling the M&D partner to recover costs and make a profit to reinvest in business operations or further research and development as applicable.

### III. Roles and Responsibilities

There are several core functions and skillsets that are required when structuring and navigating the business relationship for technology transfer, primarily when adapting, negotiating, and finalizing the TTLA document. The composition of the team draws upon several complementary functions, with varying skillsets, experiences, insights, and aptitudes. This phase can nearly entirely be managed by a project management team within IITA, assuming their team possesses business acumen and experience. The legal team is especially critical here, as their experience, insight, understanding, and ultimate sign-off of the TTLA document and arrangement are required to ratify the final agreement. At this point in the process, the project management team consists of individuals within IITA— or, potentially, one consultant remaining on the team—to see the process to a successful conclusion before shifting the focus to marketing and manufacturing support as agreed in the TTLA. Exhibit 2 outlines the essential team roles and responsibilities, but keep in mind that different resources may be required based on the specific needs of a given country.

**Exhibit 2. Illustrative Roles and Responsibilities for Structuring the Business Relationship**

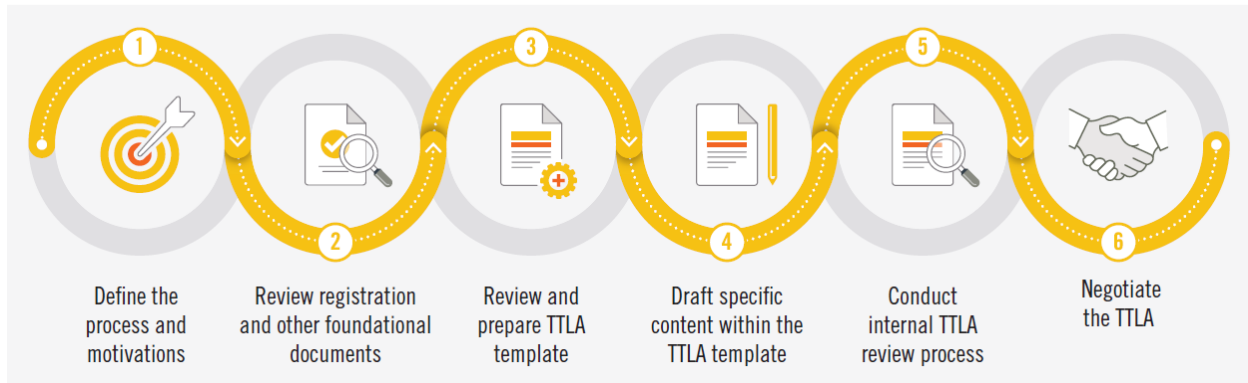
Role	Illustrative Skills	Responsibilities
<b>Business Development Team</b>	<ul style="list-style-type: none"> <li>• Expertise in agribusiness market dynamics</li> <li>• Private sector engagement experience</li> <li>• Critical thinking</li> <li>• Strong management skills</li> <li>• Understanding of corporate finance</li> </ul>	<ul style="list-style-type: none"> <li>• Establishes partnership with M&amp;D partner</li> <li>• Facilitates the initial completion of the TTLA</li> <li>• Clarifies expectations</li> <li>• Incorporates any lessons learned and/or discussion points during the previous phases of the commercialization process</li> </ul>
<b>IITA Legal Team</b>	<ul style="list-style-type: none"> <li>• Legal mastery</li> <li>• Understanding of corporate finance</li> <li>• Negotiation skills</li> <li>• Familiarity with previous TTLAs, overarching goals of CGIAR, and IITA principles</li> </ul>	<ul style="list-style-type: none"> <li>• Accounts for country context (enabling environment, regulations, laws, etc.)</li> <li>• Manages implications for IITA in-country (a macro view of other activities in-country)</li> </ul>
<b>IITA Director General or Designee</b>	<ul style="list-style-type: none"> <li>• Signatory Authority</li> </ul>	<ul style="list-style-type: none"> <li>• Signs the TTLAs, ratifying the agreement</li> </ul>
<b>Advisory Board</b>	<ul style="list-style-type: none"> <li>• Diverse experience in agribusiness, science, and international development (primarily external)</li> </ul>	<ul style="list-style-type: none"> <li>• Approves the last version of the TTLA negotiated with the licensee</li> </ul>

The private sector partner will also have a similar team dedicated to the TTLA negotiation. Often this team includes an experienced legal team and business development professionals. Their legal team will likely have similar skillsets to the IITA legal team, with additional knowledge of the firm’s business preferences, risks, and previous mergers and acquisitions or product line expansions. The business development focused team will likely be well-versed in local market dynamics, internal company policies, politics, management concerns, and/or business goals in addition to expertise in corporate finance, management, and general business acumen. All team members should be experienced, tough negotiators. It is very important to have competent and committed people on both sides of the negotiating table to ensure the development of lasting, trustworthy, and transparent relationships.

## IV. Process

This section outlines the process that has been tested and adapted by ATTC to officially transfer the Aflasafe technology to a private sector firm, which becomes the “M&D partner” for the given country or market. Exhibit 3 below shows the steps in that process, which are described in greater detail below.

**Exhibit 3. Business Relationship Structuring Process**



### Step 1. Define the Process and Motivations

<b>Objective</b>	When approaching the development, review, and negotiation process for the TTLA as the chosen structure for this business relationship, it's important to know the motivation and interest of both parties. In addition, understanding the roles, responsibilities, and process will ensure a smooth partnership process.
<b>Things to keep in mind</b>	<ul style="list-style-type: none"> <li>• The primary objective of the TTLA is to outline the relationship. The TTLA serves to document the roles, responsibilities, and expectations of both parties.</li> <li>• The role of the business development specialists, or designee focused on the negotiations and adaptation of the document, is as facilitators to support clarity of intentions and expectations. The basic tenets of the TTLA terms and conditions (especially financing expectations) should be communicated as early as possible, ideally during the investor forum and then repeated throughout the investor selection process as applicable.</li> <li>• The TTLA is a symbol of partnership. It is meant to be a transparent—not deceptive, overly legal, or turgid—document. Of course, there are protections built into the process, but those are in the interest of both parties, not meant to favor one party of the other.</li> </ul>
<b>Projected timeline and resources</b>	Ideally, this is a simple exercise that may have already been conducted during the investor selection process and the business development team can simply refamiliarize themselves. Any new or different motivations and/or interests of the parties that come up during conversations can be captured in team notes.

IITA’s motivation and interests for entering into a TTLA for the transfer of the Aflasafe technology, as discussed above, are complemented by the interests and motivations of the private sector partner, as shown in Exhibit 4 on the following page.

#### Exhibit 4. Partner Motivations for Technology Transfers

Partner	IITA	Manufacturing & Distribution Partner
Motivations	Collaboration with a private sector partner with the means, motivation, and know-how to make the product available; the interest to keep expanding and improving upon the product; the marketing strategies to reach more consumers; and the integrity to uphold IITA values and standards in how the work is approached and the quality of the product is maintained.	Collaboration with a credible public sector actor with a ready-made, trusted, and proven product that will complement and potentially expand current business activities. As an added bonus, the product will positively impact the communities and markets where the company is currently active and where it may have interests in expanding.
Benefits	Can remain involved, with the ability to monitor the growth of the business line and integrity of the product. Receives nominal royalties to cover costs associated with providing access to engineers and scientists with the extensive background in product monitoring, improvement, and technical support for Aflasafe.	Access to engineers and scientists who developed the product and have experience adapting and scaling the operations, in addition to access to previous marketing strategies and materials for the product in other countries. Can leverage IITA's convening power and relationships developed with country-level actors during the R&D and testing phases, to identify buyers and forge partnerships to drive uptake of Aflasafe.
Primary interest or goal	A transformative product is available to all at a reasonable price, including but not limited to the last mile consumer, the most vulnerable to aflatoxins. Crop quality is enhanced, health is improved, aflatoxins are mitigated.	Earn a return on investment, complementing current business lines. Potential to add a product that will help to gain market shares or provide a more integrated and comprehensive "solution" to consumers (i.e., a seed manufacturer or distributor, an input dealer and/or manufacturer), and demonstrate a socially conscious side of business through a public persona focused on health and a triple bottom line—social, environmental, and financial.

The private sector partner is investing millions of dollars into this partnership and business endeavor and thus has a lot of money at stake. IITA (and other donors) have already invested millions of dollars to get this to stage, and have their reputation at stake. Both parties simply want to trust the intentions of the other and have recourse to hold one another accountable to what was promised in the agreement (see box).

Over time, the private sector partner may want more autonomy, but in the beginning a smart business partner will want favorable terms and as much support as possible to ensure a timely return on their investment. That may influence how the private sector partner approaches the negotiation process and/or how the private sector partner initially approaches implementation of the agreement and the business endeavor. However, part of your role as a business development team member is to remind the business partner to look at this as a longer-term relationship, not just to get as much as possible at the onset of the relationship.

#### Lessons Learned

Identify and recognize motivations—and identify and share guidance and intentions—early to avoid the need for contractor guidance later on in the process and to avoid reaching a stalemate where both parties are unable to determine how to move forward together.

## Step 2. Review Registration and other foundational documents

<b>Objective</b>	Be familiar with foundational elements established as part of the registration process and previous discussions with the host government that should be conveyed as part of the TTLA.
<b>Things to keep in mind</b>	What registration elements or preferences of the local host government will impact clauses in the TTLA and the relationship or expectations between IITA and the M&D partner? What new information or contextual changes should IITA and the M&D partner factor into the TTLA preparation and expectations in the venture?
<b>Projected timeline and resources</b>	1-2 days for the business development team to refamiliarize themselves with foundational documents in anticipation of drafting the TTLA.

Frequently asked questions when reviewing these documents include:

***Q: How (and when) is Aflasafe registered locally?***

**A:** Registration in each country or region is handled by the IITA.

***Q: What is the duration of the registration and whose responsibility is it to ensure the registration is renewed?***

**A:** Since IITA registered the product, IITA is responsible for the renewal of the registration. However, it is possible this responsibility will be shifted during the assigning of roles and responsibilities in the TTLA.

***Q: Is there one product for the entire country? One product per crop? Are there regional products, or products that are viable across multiple countries?***

**A:** Historically, IITA has attempted to register any country-specific strains in addition to any regional or multi-country strains also present at that location. When multiple strains are prevalent in a given country, the scientists attempt to create a tailored product addressing as many strains as possible, realizing that the average farmer will not be able to quickly determine which strain they need to combat. In short, IITA scientists try to register as few products as possible, preferring instead to develop a super-product with the ability to combat multiple strains.

Where possible, regional products are being developed and registered across borders. As long as local governments do not include stipulations that Aflasafe must be manufactured in their country, the regional product will enable the possibility of regional manufacturing partners working with regional and/or local distribution partners. A few companies have communicated their interest in regional licenses as a much more attractive partnership option.

While a regional Aflasafe product may be possible in the future, at this stage the technology is developed for individual countries for both biological and registration reasons.

For now, the number of Aflasafe products, the properties of the products, and the registration of Aflasafe have been determined in the initial phase of innovation and development by IITA scientists. As ATTC evolves, however, the registration process will integrate feedback from the initial private sector M&D partners.

**Tips and Tricks**

Prospective investors review similar documents to have an idea of key elements that might appear in the TTLA. If the draft TTLA is ready to share within a few days of notifying the selected partner, it helps them to focus on the actual document versus the samples they've been reviewing for months in anticipation of the new partnership.

**Q: Where can I find the final registration information and/or any relevant elements of the registration process that might influence the discussions with the M&D partner?**

**A:** Registration information should be located in the legal unit at IITA in Ibadan, and with the applicable host country government’s registration office.

**Q: How is the product classified? Is VAT applied, and if so, how much, when? What agencies are responsible for the oversight and control of the product? What testing and/or random visits might the private company expect from these agencies? Are there any other unique registration factors with potential ramifications for the TTLA that may affect the M&D partner’s business opportunities?**

**A:** These are just a few of the considerations from registration that may impact business operations, taxes, marketing, or distribution. Generally, the TTLA states that the business is responsible for following local laws and requirements in operating their business, so while the details need not be included in the TTLA, the private sector partner needs to know the registration details so they can comply with the applicable laws.

### Step 3. Review and Prepare TTLA Template

<b>Objective</b>	Though there is a template for a TTLA that was developed, reviewed, and finalized over many months, using it requires thoughtful preparation for the process as well as understanding of key contextual information.
<b>Things to keep in mind</b>	A template was developed after extensive review and discussion. There is no need to reinvent the template but do take the time to become familiar with it.
<b>Projected timeline and resources</b>	The business development team should take 1-2 days to review the TTLA template and become very familiar with it. If a new TTLA were to be needed, this step could take weeks to months depending on the extent of the review by various lawyers and other parties.

**Development of the template.** This guide explains how to adapt the TTLA template that was already developed by ATTC. Through Chemonics’ corporate partnership with Arizona State University (ASU), ASU legal experts working through their innovation and technology transfer office Arizona Technology Enterprises (AzTE) advised ATTC on the best type of legal document to develop to outline the partnership details and expectations from all parties. The TTLA template was then reviewed by a lawyer recommended by ASU, identified as one of the pioneers in technology transfer with experience brokering deals between a number of public and private institutions. The language was extensively reviewed and discussed for months internally by ATTC, then with the legal department and management of IITA. The template has been approved and we expect it to be used for years to come. Any major changes to the approved clauses would require review by the IITA legal department, although, in commercializing new products, you will likely need to review and adapt the template so that all sections are applicable and appropriate. The legal department reviews all TTLAs and will note any new discrepancies (see box).

**Tips and Tricks**

Should the TTLA template need to be updated and/or a new template developed for any reason, be sure to build time for significant reviews and discussion into this process. Ideally, create or update the template at the same time as you are selecting the M&D partner so that the draft TTLA is ready to share with the selected partner within days of notifying them of the Advisory Board’s final decision.

Key sections within the TTLA include:

- Definitions and Subject Matter
- Rights and Obligations of the Parties
- Representations and Warranties
- Fees and Indemnities
- Accounting Provisions
- Confidentiality
- Term and Termination
- Miscellaneous Provisions
- Annexes: Branding guidelines; Details of technical know-how and technological services; Product quality specification; Environmental Monitoring and Mitigation Plan; Example of a final business plan

#### **Step 4. Draft specific content within the TTLA template**

<b>Objective</b>	Once your team is familiar with the TTLA outline, registration, and country context, it's time to start completing the document.
<b>Things to keep in mind</b>	Most of the information required to complete the TTLA is already available in other documents developed throughout the commercialization process.
<b>Projected timeline and resources</b>	2-3 days for the business development team to complete and review the draft TTLA if all of the preparation is completed and information is accessible.

#### **Step 4a. Complete the Licensee Description**

After the investor selection process has concluded and your team has reviewed the TTLA, there are some basic clauses in the TTLA that can be tailored using what is already known and has been shared by the private sector company. These sections include:

- General obligations of the partner, including general details of the business
- The M&D partner's final business plan, which will be annexed

#### **Step 4b. Populate the template with key country and investor-specific elements**

Key country and investor information your team can insert throughout the TTLA includes:

- Duration of license
- Renewal requirements of license
- Geographic area of license
- Production, sale, and distribution targets (based on business plan)
- Notice and termination requirements under failure to perform
- Support functions provided by IITA (technical assistance, awareness building, manufacturing, quality control, etc.)
- Quality control and standard operating procedure measures
- Branding and marking guidelines
- Contact info of both parties

#### Step 4c. Review and draft sections for special consideration and tailoring

The subtopics below refer to sections that may require additional consideration when tailoring the TLLA, as they may lead to extensive conversations with the private sector partner (see box for more guidance).

**Registration.** How the product was registered by IITA will greatly impact the contents of the TLLA, from how a product is classified, taxed, and monitored by the government to how the private sector partner can potentially market the product. When tailoring the TLLA, pay special attention to clauses in **Title II.3. and 4. General Obligations** of the private sector partner and of IITA, in addition to **Title III. 9. Legal Provisions, Compliance with Law** to determine if any edits are required to ensure consistency and cohesion with how the product is registered. These clauses purposefully do not specifically put the onus on the partner to follow the laws and policies as they may change.

**Clear performance deliverables.** To keep the partner on track and evaluate progress of Aflasafe commercialization after signature of the TLLA, it is critical to set clear milestones for the company and IITA to monitor performance toward meeting manufacturing and sales targets. It is in your interest to include the targets proposed by the investor in their final business plan, but investors will likely try to allow for maximum flexibility and lower targets. As you negotiate the performance deliverables included in the TLLA, it is critical to keep the following questions in mind:

#### Tips and Tricks

Leverage the service and support of experts to review and analyze the TLLA's content. Do not hesitate to reach out to engineers, scientists, financial analysts, business consultants, and even the IITA legal team when adapting content. The IITA legal department always has the last word, but engage with the experts on anything you're unclear on to finalize the draft.

- Do the proposed deliverables have clear descriptions that will avoid conflicts of interpretation?
- Is there a reasonable amount of time between deliverables to ensure regular performance checks without being onerous for the partners?
- Do the deliverables reflect the targets and results the investor committed to?
- Do performance deliverables include a mix of manufacturing, sales, and marketing targets?
- Are mechanisms for performance review included?

**Local labor laws and enabling environment elements.** Are there any local labor laws, IP laws, and/or enabling environment elements to be considered in adapting and adjusting the template? For example:

- What body or regulatory agency, if any, must approve a license for Aflasafe in the target country?
- What are ownership requirements for licensees in the target country? Would a multinational have an issue having a license approved?
- Are there any local legal statutes covering disputes?
- Who has decision-making authority over taxes (VAT and corporate income) for Aflasafe, and how could a waiver be obtained?

**License Arrangements.** An assessment of the pros and cons of various licensing arrangements is included in the investor selection guide in Section III and within the IITA database/toolkit. Most relevant for this phase is identifying which clauses in the TTLA may need to be adjusted to account for multiple manufacturers, or one manufacturer and multiple distribution licenses, or—as was considered in the 2019 Tanzania TTLA—one manufacturer with the stated desire of IITA to work with multiple distribution partners. If there are multiple manufacturing partners, for example, remove all references to an exclusive license and outline the territory and/or parameters allocated to each manufacturer. Key questions to address when selecting a licensing arrangement include:

- What considerations has the Advisory Board, the government, or another strategic partner discussed in regard to the production and distribution of Aflasafe in this country that may impact the preferred type of license to pursue?
- What information, analysis, or recommendations are included in the commercialization strategy regarding the most appropriate type of license?
- What has been discussed with the potential investors?
- What is the licensing strategy for the country in question? What are the market dynamics compared to what IITA is trying to achieve in this country through the various options, including:
  - Single license for manufacturing and distribution?
  - Multiple manufacturing and distribution licenses?
  - One or more manufacturing licenses, with different distribution licensee(s)?
  - Joint venture?
- Has the licensee(s)' acceptance of the license type been confirmed and reflected correctly in the agreement?

### Step 5. Conduct Internal TTLA Review Process

<b>Objective</b>	Ensure a thorough review of the TTLA, clarifying each team member's primary focus in the process.
<b>Things to keep in mind</b>	This should be a timely but detailed review, as this document is fundamental to the relationship between the parties. A fresh set of legal eyes is important for both parties to ensure everyone is comfortable moving forward.
<b>Projected timeline and resources</b>	Plan for 1-2 weeks of review and discussion between the business development team and the IITA legal team. However, this could take upwards of a month if the team is engaged with other work or there are significant deviations.

As noted in Exhibit 2 regarding the assigning of roles and responsibilities, the IITA legal team is a fundamental partner in the process to finalize the TTLA document before sharing it with the selected M&D partner. After finalizing negotiations and with the team lead's agreement, share the document with the IITA legal team for review. The IITA legal team reviews the document for any substantive deviations from the template, and to ensure the agreement respects all of the relevant local laws, any registration and/or agreements with the host country, and the CGIAR Principles. Depending on the level of deviation and/or special new clauses, the review by the IITA legal team takes, on average, about a week or two, but it could take more than a month if there is significant deviation from the current template and language for any reason.

## Step 6. Negotiate the TTLA

<b>Objective</b>	This final step involves a constant dialogue between the parties to come to agreement on the final language included in the TTLA.
<b>Things to keep in mind</b>	Negotiation with the M&D partner is more than just completing a step, as this relationship will last for years. This step is critical to establish clear understanding of expectations, intentions, and the character of each party going forward.
<b>Projected timeline and resources</b>	This process could take anywhere from 2-8 weeks, depending on the details of the discussion. The business development team leads the negotiations, and involves the IITA legal team as necessary. For any major deviations from what was approved by the Advisory Board, the business development team may need to consult with the Board—or at least provide advance notice.

The next steps in the process include: i) sharing the draft TTLA with the partner for comments; ii) reviewing comments, providing responses, and negotiating differences; iii) soliciting feedback from local or international IP counsel if there are any major changes to the structure and/or foundation of the TTLA; and iv) finalizing the TTLA.

In ATTC's experience, larger companies with multiple business lines, usually in numerous markets, have had the most extensive requests during the negotiation process (see box). This emerging trend is most likely attributable to a few simple factors: experience confronting and mitigating myriad situations and worse case scenarios, a clear understanding of the risk and patient work involved to create the demand for this new product, and confidence in their business and their virtues as a strong business partner. All of these factors may lead these companies to ask for their ideal terms. Your role is to communicate IITA's terms and attempt to negotiate to a common ground. Ultimately, the IITA legal department makes the final determinations of acceptable terms and conditions.

### Tips and Tricks

Negotiations can be lengthy. When drafting the TTLA, note internally any minimum or acceptable limits for specific terms and conditions, as well as for the timeframe for negotiations. Without boundaries to set as goals, negotiations could go on forever.

The TTLA, as a written document outlining the relationship, is the opportunity to capture any discussions and expectations to date (see box), as it will be the only enforceable way to follow up on intentions discussed. Please remember to review each clause—the private sector partner's legal team certainly will!

### Lessons Learned

In addition to the TTLA encapsulating the final determinations in the negotiations, for audit purposes, IITA is required to keep all correspondence with the companies. In order to avoid confusion, ask the investor(s) to propose in writing any wording changes they'd like to include. Should you encounter what feels like a new request, it might be a subject that was broached in other negotiations. Senior team members or the IITA legal team may have access to the confidential correspondence with previous partners and may be able to help quickly determine how to handle the requests based on previous experiences.

Remember, there will always be tradeoffs; as concessions are made in one area, it may be necessary to adjust other terms. For example, if royalty payments are adjusted downward, then service fees may need to be included. The final topics below outline the most frequently discussed sections during the negotiations with the private sector partners. The TTLA template, while a solid foundation, will no doubt be adjusted over time, as lessons learned from implementation are assessed and incorporated into TTLAs to reflect new practices and approaches to the relationship. An agreement is just the beginning. Implementation and management of the

partnership—and holding one another accountable to what was agreed upon—is the crux of the relationship and will no doubt influence future changes to the TTLA.

The IITA legal team will be involved in the negotiations as needed, as counsel for any deviations and/or tradeoffs. The final step after negotiations have successfully concluded is to share the TTLA with the Advisory Board, noting any significant deviations from the TTLA template, either in accordance with the guidance provided by the Board (e.g., insistence on naming distribution partners) or deviation based on the negotiations with the private sector partner (e.g., service fees included in addition to referencing a lower royalty rate). When flagging these changes, it's critical to note the consensus and coordination with the IITA legal team with the objective of mitigating the reopening of the negotiations with the private sector partner. Should there be significant deviations from the TTLA template, it's wise to provide advance notice to the Chairman of the Board as he can help to indicate if the changes are too radical and would need Board approval as part of the negotiation process—as opposed to a final ratification. Once the Advisory Board ratifies the TTLA, it is signed by both parties, the Director General on behalf of IITA, and the CEO on behalf of the private sector partner. With documented approvals from the IITA legal team and the Advisory Board there is no need for the Director General's office to further ratify the TTLA before signature. To date, a signing ceremony has proven to be an effective event signaling the public commencement of the partnership.

***Sections for special consideration: most frequently discussed sections during the negotiations with private sector partners***

The subtopics found below are issues or key sections to consider during the negotiation process, either because of the strategic interest of IITA and the Advisory Board, or because they are of great interest within the private sector partner's business strategy. Become familiar with these topics early in the investor selection process as they will help frame conversations and understand underlying motivations or concerns by both parties that may not be entirely clear until later in the process.

***Exclusivity.*** Private sector partners are often confused by IITA's concerns and its desire to select multiple manufacturing and distribution partners in a country. The private sector partner is investing millions of dollars, isn't that sufficient commitment to the product and the relationship? Actually, the answer is no.

While the financial risk is a demonstration of sincere commitment to the product and a genuine business opportunity, IITA is also taking a great reputational risk that cannot be written off in a balance sheet statement. Potential partners have not paid for the R&D required to develop the product; the production guidance developed through purposeful trial and error; the market studies; government lobbying; or even initial marketing guidance, value propositions, and initial consumer profiles. IITA, with significant support from the Bill & Melinda Gates Foundation, USAID, and public resources, has invested heavily in the development of this product, and as such, the Advisory Board is well-justified in exploring different options.

Partners are also very concerned about the duration of the exclusive license, and often attempt to request an exclusive license for 10 years, or at least a guarantee that they can extend the exclusivity for another five to 10 years. At this point, there is no guarantee that the exclusive license will be extended. However, if terms and conditions are met as outlined in the agreement, it is in the interest of both parties to extend the license, exclusive or not, for another five to 10 years.

If a non-exclusive agreement is signed, either initially or after the first five-year period, partners will want to know more about their competition and the terms and conditions that govern their competitors, i.e., do they have an identical TTLA, or are there any differences, from limited geographic reach, limited years (less than five years), or limited scope (distribution versus distribution and manufacturing)? In the spirit of transparency, we recommend sharing the basic information with all parties, since IITA may need to serve as a mediator between the parties, or at least mitigate any public disputes between the parties. (See boxes for additional tips).

**Tips and Tricks**

If the company asks for a concession in one area that seems too difficult to agree to, don't just say no. Instead, try to estimate the economic value of that concession and ask for something of equal value in return in another area of the business, often represented in a separate reference in the TTLA.

**Branding.** The two elements of branding consistency required by IITA across countries and markets are using the name Aflasafe, and including the IITA logo. Reference to IITA brings credibility to the product, communicating that the product was developed by a scientific breakthrough, while also growing IITA's brand recognition as more of a household name or stamp of credibility. Building name recognition across Africa will reinforce demand for this unique product.

Co-branding is not only possible but encouraged as the selected partners were, in part, selected for their presence, name recognition, and credibility in the market. Their experience in knowing the market and knowing customer preferences should only strengthen the branding and marketing.

As the registered name of the Aflasafe product and country-specific version (e.g., TZ 01, SN 01, etc.) is determined by scientists, we do not encourage highlighting the country-specific label name for the purpose of marketing or sales. The registered label by IITA (e.g., SN 01) might not necessarily be the right fit when introducing the product in a specific market, since it brings no real value or distinction to the consumers, it only helps IITA classify the Aflasafe variety (or in rare cases varieties) in each country. Partners are required to find the right commercial branding of the product considering the context and the experience of the companies involved. Modifications can be made to the registered name of the product or a marketing campaign can be developed without referencing the officially registered product name of, for example, MW 01 in Malawi, or SN 01 in Senegambia. Additional branding expectations are referenced in the TTLA template, which can be found in the IITA database/toolkit, as it is also included in each TTLA as an annex. It is important to note is that for each set of negotiations, branding constituted a significant discussion initiated by the private sector partner.

**Tips and Tricks**

If you consider alternative royalty structures, remember that if the payment to IITA, i.e., cash flow, is more predictable and certain, IITA could accept a lower total payment, and vice versa.

**Royalty.** The royalty is the minimal amount paid to IITA to cover costs for engineers, scientists, and business development specialists to support the private sector partner in tailoring their processes, workflow, and strategies to develop this new business line. During the investor selection process, many companies have asked what the \$0.05/kg royalty fee is, what does it represent, and is it negotiable? The royalties serve to cover the cost of the services as outlined in the TTLA:

- Maintenance of the registration
- Improvement of the product and monitoring
- Auditing of the manufacturing process
- Targeted assistance when required

The time and resources required to support each new business endeavor is calculated to be significantly more than the approximate \$300,000 that a company might pay in royalties over the first five years of operations. The ongoing royalty payment helps fund IITA's ability to continue to support more businesses around Africa, extending the product to the last mile (see boxes).

In a context when donors are not present, a minimum income is required to cover the costs of services from the specialists, engineers, and scientists. These specialists, as outlined in the TTLA, need to be available and accessible to support the M&D partners in real time. Without a royalty payment, under a potential pay-for-services arrangement, there is no guarantee of income flow to maintain the BIP or these specialists.

**Tips and Tricks**

Involve and engage the IITA legal department during the negotiation process. The decision-maker (the legal department or, in some cases, the Advisory Board) must participate in the negotiation.

One change that has been made to the royalty payments policy, based on requests and feedback from the private sector partners, is how to calculate them. Instead of a portion of production, the royalty payments could be a portion of sales, when and if there is a mechanism to easily track confirmed sales. From a legal point of view, basing royalties on production is relatively easy to track, whereas sales revenue is more difficult to monitor and verify. However, since this is a new, unestablished product, IITA has accepted this request.

Many potential partners have also requested an arrangement similar to the one being offered by Purdue University for the commercialization of Purdue Improved Crop Storage bags: to pay a royalty only after breaking even with the business line showing a profit. However, this arrangement is not viable for IITA, which needs the royalty funds to keep providing the requisite support services and keep innovating and expanding Aflasafe in more countries.

**Private sector partners' expectations of future support from IITA.** Private sector partners often ask "What can I really expect in terms of ongoing support from IITA?" In addition to outlining and explaining the services that are covered by the royalty payment, the private sector partner is often trying to ascertain what government advocacy support or marketing support IITA will be able to provide on an ongoing basis. IITA will need to continue to examine these questions, as the ATTC initiative concludes.

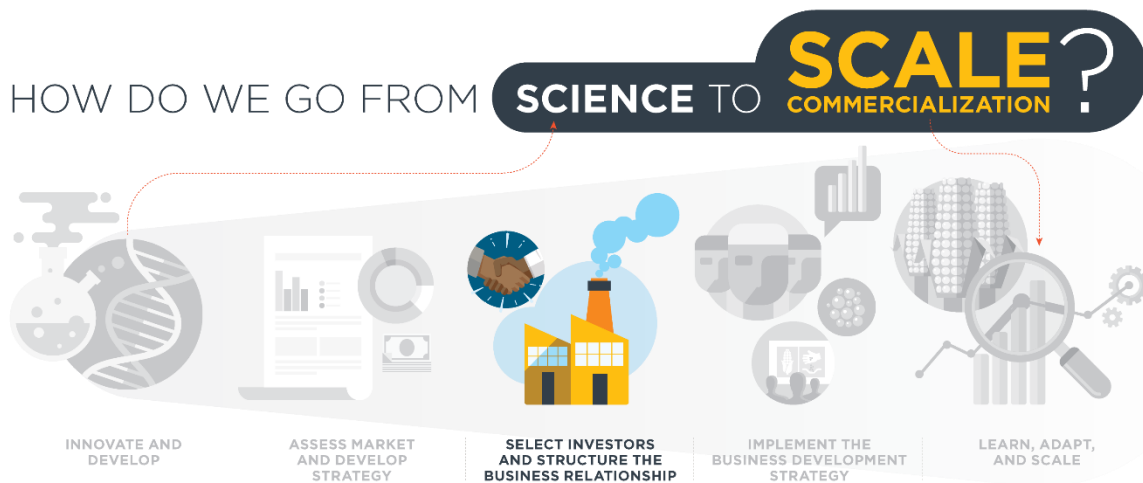
**Accountability and monitoring of performance.** Clauses regarding termination, force majeure, and dispute resolutions, as currently written, are the culmination of multiple discussions. IITA needs the ability to revoke the license completely for nonperformance or egregious misrepresentation of the product, which could impact its reputation. However, IITA acting as a public institution, will attempt to work more patiently with partners than two private sector partners would. Understanding that it may take time for the M&D partner to penetrate the market, if the company falls short of sales targets, IITA will most likely adjust the license to be non-exclusive before a license is revoked completely. As a public research institution, IITA will seek to understand the driving factors behind the lack of traction and will attempt to support the partner to address and mitigate those factors before moving on to another partnership. This makes the competitive investor selection process all the more critical, pointing to the importance of selecting a partner worthy of the patient commitment of a public research institution's support.

#### **Tips and Tricks**

Calls and meetings between the two parties should be prioritized to discuss and clear up any contentious points or other issues in the negotiation process.

## **V. IITA Database/Toolkit Documents, Templates and Samples**

- **Commercialization Partnership Options for Aflasafe**
- **Licensing Arrangements with Private Sector Partners**
- **TTLA Template (including all annexes)**



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