



FEED THE FUTURE GLOBAL BIOTECH POTATO PARTNERSHIP

Annual Report

October 1, 2021 – September 30, 2022

Lead University:
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Principal Investigator:



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ACRONYMS

AATF	African Agricultural Technology Foundation
AOR	Agreement Officer Representative
BARI	Bangladesh Agricultural Research Institute
BCC	Biosafety Core Committee
BecA	Bioscience eastern and central Africa
CFT	Confined Field Trial
CIP	The International Potato Center
DMP	Data Management Plan
DR	Disease-resistant
FDA	Food and Drug Administration
FFB	Farming Future Bangladesh
GAANTRY	Gene Assembly in Agrobacterium by Nucleic acid Transfer using Recombinase technology
GFSS	Global Food Security Strategy
GLR	Global Resource Lead
GM	Genetically modified
IAARD	Indonesian Agency for Agriculture Research and Development
IBC	Institutional Biosafety Committee
ICABIOGRAD	Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development
IndoBIC	Indonesian Biotechnology Information Center
ILRI	International Livestock Research Institute
ISBR	International Society for Biosafety Research
IVEGRI	Indonesia Vegetable Research Institute
KALRO	Kenya Agricultural and Livestock Research Organization
LB	Late Blight
LBR	Late Blight Resistant
MLT	Multilocation Trials
M&E	Monitoring and Evaluation
MoA	Ministry of Agriculture
MoEFCC	Ministry of Environment, Forest, and Climate Change
MSU	Michigan State University
NBA	National Biosafety Authority
NBMA	National Biosafety Management Agency
NCB	National Committee on Biosafety
NRIA	National Research and Innovation Agency
NRCRI	National Root Crops Research Institute
NTCCB	National Technical Committee on Crop Biotechnology

PCR	Polymerase Chain Reaction
PI	Principal Investigator
PSC	Personal Service Contractor
ROAF	Research Organization for Agriculture and Food
SEAMEO BIOTROP	Southeast Asian Regional Centre for Tropical Biology
SOP	Standard Operating Procedures
TAB	Technical Advisory Board
T-DNA	Transfer DNA
TOC	Theory of Change
TSL	The Sainsbury Laboratory
UI	The University of Idaho
UMN	The University of Minnesota
USAID	United States Agency for International Development
USDA	United States Department of Agriculture

I. EXECUTIVE SUMMARY

The Feed the Future Global Biotech Potato Partnership is a five-year initiative implemented by Michigan State University (MSU) that focuses on the use of innovative research to promote a robust potato value chain through the commercialization of the 3 R-gene late blight resistant (LBR) potato in Bangladesh, Indonesia, Kenya, and Nigeria. Despite beginning project activities during the middle of the COVID-19 pandemic, activities in Year 1 set a solid foundation for significant progress toward achievements of project objectives.

Highlights of Technical Activities and Results

In Bangladesh, a Multilocation Trial (MLT) application for trials in 6 locations was submitted to regulatory officials and is awaiting approval. Activities began to conduct stakeholder mapping of the potato value chain and communication and advocacy work was launched in Year 1. In Indonesia, seed multiplication was conducted to produce seed for planting in the MLTs in Year 2 and most of the molecular characterization for the three lead Granola events was completed. In Kenya, training on biosafety and Standard Operating Procedures (SOPs) for Confined Field Trial (CFT) management was initiated for all field staff prior to transplanting the transgenic and non-transgenic potatoes. The CFT was planted, and scientists started the survey of the pathogen population by collecting samples for genotyping. In Nigeria, tuber seeds consisting of transgenic and non-transgenic potatoes from Kenya and the United States were shipped and planted in the field for testing resistance to late blight. The ongoing CFT has confirmed this with early signs of infection and all non-transgenic varieties being killed whereas all 3 R-gene LBR potatoes remained unaffected. Project-level activities included the development and launch of the Technical Advisory Board, which reviews the quality and pertinence of the science and technologies used in the project and provides strategic guidance on multiple topics. The project also established and maintained the project website and the social media platform. Project setbacks related to in-country government restructuring and procedures for establishing subaward agreements resulted in the delay in subaward agreements in Indonesia and Bangladesh.

Upcoming Planned Activities

In Year 2 project scientists from each country will complete a 1-month internship in the laboratories at BecA-Nairobi and begin transformation work on the 2nd generation of disease resistant potato in their respective laboratories. The project will also conduct an ex-ante socioeconomic assessment and market analysis for Bangladesh and Kenya, which will include an in-country 'expert elicitation' workshop. There is a multi-discipline coordinated effort between the project team and the four in-country teams of biotech scientists, plant pathologists, and economists to conduct the research and work with regulatory and communication activities to identify the lead events for deregulation and distribution to growers. Multilocation CFTs are being conducted or planned for each of the four target countries. Data from each trial will be used in the regulatory dossiers that will be submitted.

II. PROJECT OVERVIEW

The Feed the Future Global Biotech Potato Partnership is a five-year initiative implemented by Michigan State University (MSU) that focuses on the use of innovative research to promote a robust potato value chain through the commercialization of the 3 R-gene late blight resistant (LBR) potato in Bangladesh, Indonesia, Kenya, and Nigeria. The project consists of the following partners: The International Potato Center (CIP), The University of Minnesota (UMN), The University of Idaho (UI), The Bangladesh Agricultural Research Institute (BARI), The Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development (ICABIOGRAD), The Kenya Agricultural and Livestock Research Organization (KALRO), The National Root Crops Research Institute, Umudike (NRCRI), and The African Agricultural Technology Foundation (AATF). The Global Biotech Potato Partnership project, including its robust team of experts and partners, represents a distinctive contribution to global agricultural biotechnology efforts and addresses the overarching objectives of the Global Food Security Strategy (GFSS). The LBR potato achieves inclusive and sustainable agriculture-led growth by improving the lives of smallholder farmers, both women, and men, through increased technology options, improved crop yields, reduced fungicide input costs, and reduced exposure to harmful chemicals. The project will help strengthen resilience among people and systems through improved crop management from seed to post-harvest storage.

The project's overarching goal is to contribute to sustainably reducing global hunger, malnutrition, and poverty and help Bangladesh, Indonesia, Kenya, and Nigeria accelerate their progress toward self-reliance. The project activities span across five workstreams: 1) 3 R-gene LBR potato field trials, 2) Regulatory submission for general release of the 3 R-gene LBR potato, 3) Product deployment through biotech seed system and stewardship, 4) Second-generation disease-resistant (DR) potato; and 5) Communication and advocacy. This annual report summarizes the achievements and progress towards the project's objectives and covers year one: October 1, 2021, to September 30, 2022.

Country-Specific Updates

Bangladesh

Award activities implemented during Year I include the initiation of the subaward agreement by MSU with BARI, which is still pending. Additionally, Farming Future Bangladesh (FFB) finalized a workplan and service contract with MSU for Year I activities. FFB provides leadership in Bangladesh for communications and advocacy and logistical support for the project as the Country Co-Lead with the BARI Principal Investigator (PI). FFB worked with BARI and project leadership to recruit a Senior Manager for Communications and Advocacy, and a BARI Research Associate.

An application for a single-location Confined Field Trial (CFT), submitted by BARI before the official start of the project, was forwarded by the National Technical Committee on Crop

Biotechnology (NTCCB) in the Ministry of Agriculture (MoA) to the National Committee on Biosafety (NCB) in the Ministry of Environment, Forest, and Climate Change (MoEFCC) in October 2021. The application was not approved in time to plant the single location trial, and the NCB agreed to consider an application to plant Multilocation Trials (MLTs) in 2022. An MLT application for trials in 6 locations was submitted to the BARI Institutional Biosafety Committee (IBC) in May, passed the review of the BARI IBC and the NTCCB in the MoA and reached the MoEFCC/NCB in August. This application is awaiting review and approval by the NCB in time to plant the CFTs in November 2022. The team in the Biotechnology Division at BARI has been maintaining the two 3 R-gene Diamant events in tissue culture, as has MSU. Seed tubers for the November field trials were produced in the greenhouses at BARI and in the NFT production system at MSU. The Global Resource Lead for Product Development and Technical Support at MSU completed most of the molecular characterization for the two lead Diamant events.



The research team at BARI conducted detached leaf bioassays on the 3 R-gene Diamant events in July 2021 to prepare for a confined field trial permit application for the GBPP in Bangladesh.

In Year 2, the project plans to plant MLTs at four locations, pending approval by the regulatory authority, for performance evaluation and collection of regulatory data, and will collect isolates of the late blight pathogen from the fields for genotyping. The project will conduct an ex-ante socioeconomic assessment and market analysis for Bangladesh, which will include an in-country 'expert elicitation' workshop, facilitated by the Global Resource Lead for Socioeconomic and Market Analysis. A project scientist from BARI will complete a 1-month internship in the laboratories at BecA-Nairobi and begin transformation work on the 2nd generation of disease resistant potato in the BARI labs. There will be a small launch event after the field trials have been planted. The Project Director, Deputy Director/Regulatory Lead, and Global Resource Lead for Communication and

Advocacy will plan to attend the launch and visit the field trials. The Deputy Director/Regulatory Lead is planning multiple visits during Year 2 and will meet with key stakeholders.

Indonesia

Award activities implemented during this period of performance include the initiation of the

subaward by MSU with ICABIOGRAD, which was pending final in-country approval. However, a major reorganization in the Indonesian government took place as of August 2022 and all project scientists were moved from the Indonesian Agency for Agriculture Research and Development (IAARD) to a new research and development agency, the National Research and Innovation Agency (NRIA). This reorganization requires dissolution of the agreement between ICABIOGRAD/IAARD and MSU and a new agreement between the Research Organization for Agriculture and Food (ROAF)/NRIA. This new agreement had not been executed by the end of Year 1.

At the beginning of Year 1, ICABIOGRAD submitted a revised MLTs application, and the permit for the MLTs was granted in January 2022. The planting of the MLTs has been postponed to Quarter 2 Year 2 due to the government reorganization and delayed finalization of the subaward agreement. A scope of work and service contract with the Country co-Lead has been finalized and the Country co-Lead has been assisting the project to navigate the government reorganization. The project was able to conduct seed multiplication in the field in Lembang to produce seed for planting in the MLTs in Quarter 2 Year 2. The Global Resource Lead for Product Development and Technical Support at MSU completed most of the molecular characterization for the three lead Granola events. Completion of a contract with SEAMEO BIOTROP/Indonesian Biotechnology Information Center (IndoBIC) for communications activities is ongoing.



The Deputy Director-Asia and the Global Resource Lead for Disease Resistance Management met with the project's research team and new project partners from the Research Organization for Agriculture and Food (ROAF) in Indonesia in July 2022.

In Year 2, the project plans to plant MLTs at four locations for performance evaluation and collection of regulatory data and will collect isolates of the late blight pathogen from the fields for genotyping. A project scientist from ROAF will complete a 1-month internship in the laboratories at BecA-Nairobi and begin transformation work on the 2nd generation of disease resistant potato in the labs in Indonesia. The Deputy Director/Regulatory Lead is planning multiple visits during Year 2 and will meet with key stakeholders. The Global Resource Lead for Disease Resistance Management will also travel to Indonesia to facilitate the isolate collections.

Kenya

The inclusion of Kenya as a partner country occurred during the first quarter of Year 1 and KALRO agreed to participate on the project as the lead national research organization. Award activities implemented during this period of performance focused first on completing the subaward agreement. An application to conduct a CFT was then submitted by KALRO to the National Biosafety Authority (NBA). The 3 R-gene LBR potatoes and their respective non-transgenic comparators were transferred from *in vitro* to the greenhouse for seed production. After harvest and germination, the CFT planting materials were established in pots in the KALRO greenhouse until permits were granted to plant the CFT.



The Global Resource Lead for Disease Resistance Management works with the teams from KALRO and CIP on trial management software in preparation for multilocation trials.

A project launch meeting took place with Kenyan stakeholders at KALRO headquarters with the presence of the head of NBA and USAID/Kenya Mission representation. Training on biosafety and Standard Operating Procedures (SOPs) for CFT management was initiated for all field staff prior to transplanting the transgenic and non-transgenic potatoes from the KALRO biosafety greenhouse to the [REDACTED] CFT site. Due to late planting, late blight (LB) disease was not severe in the CFT, but lesions were observed only on the non-transgenic plants. The in-country scientists started the survey of the pathogen population by

collecting samples for genotyping. Meanwhile, the CIP team continued the molecular and trait characterization of a variety 'Jalene' which has wide potential to be introduced throughout Africa. An application was submitted to the regulatory authorities for additional trial locations and the permit was granted at the end of Year 1.

In Year 2, field trials will include three locations in two seasons to collect regulatory data with up to 4 transgenic 3 R-gene LBR varieties. During the peak of LB disease, stakeholder visits will be organized including farmers, distributors, seed enterprise, and academics. At least one lead transgenic event for deregulation will be identified based on the regulatory data collected. The project will conduct an ex-ante socioeconomic assessment and market analysis for Kenya, which will include an in-country 'expert elicitation' workshop, facilitated by the Global Resource Lead for Socioeconomic and Market Analysis. A project scientist from KALRO will complete a 1-month internship in the laboratories at BecA-Nairobi and begin transformation work on the 2nd generation of disease resistant potato in the labs in Kenya. The Deputy

Director – Africa is planning multiple visits during Year 2 and will meet with key stakeholders. The Global Resource Leads for Regulatory Affairs, Disease Resistance Management, and Communication and Advocacy will also visit Kenya in Year 2.

Nigeria

The lead national research organization in Nigeria partnering on the project is NRCRI who brings expertise in potato research. Year 1 activities in Nigeria focused on finalizing the subaward agreement and submitting permit applications to handle and test in the field the 3 R-gene LBR potatoes. The National Biosafety Management Agency (NBMA) granted permits to NRCRI to work with genetically engineered potatoes. NRCRI organized the Nigerian project launch meeting, which was attended by representative of the potato sector, local authorities, and NBMA.

Tuber seeds consisting of transgenic and non-transgenic potatoes from Kenya and the United States were shipped with the appropriate permits. The shipped seed tubers were planted in the field in Jos for testing resistance to LB. During the rainy season, LB disease was particularly severe this year with reports in the local press of large losses of potato due to LB. The ongoing CFT has confirmed this with early signs of infection and all non-transgenic varieties being killed whereas all 3 R-gene LBR potatoes remained unaffected. The field trial was not completed before the end of Year 1. The in-country team started the collection of pathogen samples.

In Year 2, a ‘Green Day’ field visit will be organized for local potato specialists. The CFT will be harvested and preliminary evaluation of the merits and potential for adoption of the 4 varieties tested. A stakeholder visit will be organized at harvest (‘Brown Day’). Meanwhile, NRCRI scientists are propagating plant materials in the screenhouse for producing the tuber seeds for the MLT which will be planted in Quarter 4 of Year 2. Establishing the other 2 locations, training on biosafety, and updating SOPs will also be conducted in Year 2. A project planning meeting will be organized including participation from key potato stakeholders, NBMA, and the USAID/Nigeria Mission. A project scientist from NRCRI will complete a 1-month internship in the laboratories at BecA-Nairobi and begin transformation work on the 2nd generation of disease resistant potato in the labs at NRCRI. The Deputy Director – Africa and the Global Resource Leads for Regulatory Affairs and Disease Resistance Management will visit Nigeria in Year 2.

III. TECHNICAL REPORT

3.1. Workstream 1: 3 R-gene LBR Potato Field Trials

The objective of this workstream is to demonstrate the commercial potential of the 3-R gene LBR potato, build technical capacity for late blight resistant potato field trials, and build regulatory capacity for biotech crop field trials. Activities for Year 1 are outlined in the sections

below.

3.1.1. Major Activities and Achievements

Bangladesh

- Before the start of the project, BARI submitted a revised version of the single-location CFT application, including a report from the greenhouse 'Contained Trial' carried out April-August 2021 (completed as part of the Feed the Future Biotechnology Potato Partnership project) as required by the NCB. This application was approved by the BARI IBC and the NTCCB in MoA but was not approved by the NCB in MoEFCC in time to plant in November 2021 (the 2021-2022 potato season).
- The BARI Project PI successfully negotiated an agreement with the NCB to consider an application for planting MLTs in November 2022. A revised CFT application for MLTs to include up to 6 locations was submitted by BARI for planting in November 2022. This application was approved by the BARI IBC and the NTCCB in MoA and sent to the NCB in MOEFCC at the end of August 2022. The application has yet to be approved by the NCB.
- A brief justification for the presence of the 3 R-genes in the Diamant events was prepared and submitted as an appendix with the MLTs application, in response to questions from the review of the initial confined field trial application by the Biosafety Core Committee (BCC), a technical committee under the NCB. The primers and protocol obtained from Simplot Plant Sciences to demonstrate the presence of the 3 genes in the TDNA were tested in the labs at MSU, and the primers and protocol were shared with BARI.
- A brief assessment of toxicity and nontarget organism effects of R-genes in late blight resistant potato was prepared and submitted as an appendix with the MLT application, in response to the review by the BCC of the initial CFT application.
- Seed multiplication was planted for the 2 Diamant events and non-GM Diamant in the greenhouse at BARI for harvest in Quarter 1 of Year 2, to be used for planting in November 2022.
- NFT minitubers of the two Diamant events and non-GM Diamant were also produced by MSU in Cycle A March-August 2022 for shipping to Bangladesh and planting in November 2022.
- Plants of the two lead events were maintained in vitro at BARI and at MSU. MSU verified identity of plants in tissue culture using molecular analysis.
- A Research Associate was hired by FFB to work in the laboratories of the Biotechnology Division at BARI on tissue culture and other tasks.
- CFTs were planted at the MSU research farms for agronomic performance and for late blight resistance of the two Diamant events and the non-GM Diamant. These trials will

be completed in Quarter 1 of Year 2 and will provide backup data on performance for the trials that will be conducted in-country.

- The project had also planned to collect and characterize pathogen strains during the 2021-2022 potato season, but this could not be accomplished because the subaward agreement between MSU and BARI has not been finalized by BARI.

Indonesia

- An application for MLTs was submitted before the start of the project. The Indonesia team submitted a revised version of the application based on the initial review by the Biosafety Committee, and the permit for the MLTs was received in January 2022. The MLTs could not be planted as planned due to the delayed finalization of the subaward agreement.
- Seed multiplication was planted for the 3 Granola events and non-GM Granola in the field at the Indonesia Vegetable Research Institute (IVEGRI) in Lembang for harvest in Quarter 1 of Year 2, and for planting in Quarter 2 of Year 2.
- NFT minituber production of the 3 Granola Events was initiated at MSU in July 2022 Cycle B for shipping and planting in MLTs or in seed multiplication in Indonesia in Quarter 2 of Year 2.
- Plants of the two lead events were maintained in vitro at MSU. Tissue culture plantlets were not shipped to Indonesia in Year 1 as planned due to the delayed finalization of the subaward agreement.
- DNA primers and detailed instructions were sent to the research team in Indonesia for Granola event identity checks, although this activity is delayed due to the delayed finalization of the subaward agreement. MSU verified identity of plants in tissue culture using this molecular analysis.
- Confined field trials were planted at MSU research farms for agronomic performance and for late blight resistance of the three Granola events and the non-GM Granola. These trials will be completed in Quarter 1 of Year 2 and will provide backup data on performance for the trials that will be conducted in-country.
- The project had planned to collect and characterize pathogen strains during Year 1, but this could not be accomplished because of the delayed finalization of the subaward agreement.
- The Deputy Director–Asia and the Global Resource Lead for Disease Resistance Management traveled to Indonesia in July 2022 to meet with project partners and discuss plans for the MLTs, regulatory data collection, and isolate collection, and to work on a revised workplan and budget for the subaward agreement with the new agency.

Kenya

- An application permit to conduct the CFT was granted by NBA.
- Transgenic and non-transgenic seed tubers from four local varieties (Desiree, Victoria/Asante, Shangji, Tigoni) were produced in the biosafety greenhouse at [REDACTED]
- Pathology activities (baseline information, new collection sites, procedures) were implemented and 3 potato regions were sampled.
- Molecular and trait characterization of the variety Jalene made substantial progress towards identification of candidate lead transgenic events.
- The project launch meeting was successfully organized with the presence of national potato experts, NBA, and USAID/Kenya.
- Tuber seeds of 3 R-gene LBR potato (4 varieties) and their non-transgenic comparators were planted in a CFT in [REDACTED]
- Field observations of plant growth and LB incidence were conducted.
- SOPs and SOP Forms were reviewed and adjusted based upon the SOPs used in Bangladesh and Indonesia.
- An application was submitted to the regulatory authorities for additional trial locations and the permit was granted at the end of Year I.



Confined field trial at the [REDACTED] in Kenya

Nigeria

- Certification to work with genetically engineered potato was obtained from NBMA.
- The project launch meeting provided the opportunity to introduce project activities to local potato experts, farmers, government authorities, and the USAID/Nigeria Mission.
- Tuber seeds from Kenya and the United States were received by NRCRI and immediately planted in the approved CFT site.
- LB severity and incidence were recorded. The non-transgenic potatoes were killed



Confined field trial at the NRCRI [REDACTED] in Nigeria

by LB, whereas all transgenic 3 R-gene LBR potatoes remained unharmed.

- Imported tuber seeds were planted in the screenhouse within the CFT site to produce the tuber seeds for the Year 2 trials (the regulatory trials from 3 locations).

3.1.2. Implementation Challenges

Bangladesh

- There are two major implementation challenges in Bangladesh:
 - The slow regulatory approval process prevented the project from proceeding with a single location trial at BARI in November 2021 as planned. However, the NCB did agree to consider an application for MLTs in the next season, and the overall timeline for the project will not be impeded if the permit for the MLTs is granted in time to plant in November 2022. Unfortunately, due to the slow regulatory process, a permit for the MLTs had not yet been granted by the end of Year 1 and it will be a challenge to plant trials in multiple locations in November 2022 with minimal time to prepare.
 - The subaward agreement between BARI and MSU has not been finalized by BARI. The in-country work accomplished by BARI for Workstream 1 in Year 1 has been completed without access to funds for the project. Some work has been delayed, such as the pathogen survey and shipment of seed tubers from MSU. The delayed execution of the subaward agreement and access to funds presents a serious challenge for preparation and conduct of the MLTs planned for November 2022.

Indonesia

- A major implementation challenge for the project in Indonesia has been presented by the unexpected reorganization of the government which took effect in August. The reorganization necessitates dissolution of the existing subaward agreement with IAARD and the execution of a new subaward agreement for the project with a new agency for research and development. Unfortunately, a new subaward agreement was not yet completed by the end of Year 1. The MLTs initially planned for planting beginning in Quarter 1 of Year 1 are now postponed until Quarter 2 of Year 2.

Kenya

- The biosafety permit from the NBA in Kenya for confined field trials to test transgenic potatoes already approved for contained use required an unanticipated new full review, which delayed planting. This led the CFT to be planted off season and, thus, with little incidence of LB disease. However, the NBA's review and approval of the single location application and subsequent planting streamlined the process for granting new locations for the next year.

Nigeria

- The potato plants from the variety Desiree and the lead 3 R-gene transgenic event Des.52 were infected with other pathogens due to poorly sterilized soil at the

ILRI/BecA greenhouse. This prevented this variety from be tested in Nigeria. Tuber seeds will be shipped in Year 2.

3.1.3. Expected Activities for the Upcoming Year

Bangladesh

- Pending approval from the NCB, MLTs will be planted for evaluation of performance and collection of regulatory data.
- Seed of the two 3 R-gene Diamant events multiplied in the greenhouses at the Biotechnology Division in BARI will be harvested and seed from the NFT production system at MSU will imported for planting in the MLT trials.
- A new application for a second round of MLTs to plant in November 2023 will be submitted, and seed for these trials will multiplied in the greenhouses at BARI and in NFT production at MSU.
- Pathogen isolates will be collected from the potato growing regions during the potato growing season and genotyped in the laboratory at the University of Idaho.

Indonesia

- CFTs will be conducted in four locations to evaluate performance and collect regulatory data.
- Seed of the three 3 R-gene Granola events will be multiplied in the greenhouses at the Biotech Division in BARI will be harvested and seed from the NFT production system at MSU will imported for planting in the MLT trials.
- Pathogen isolates will be collected from Sumatra and N. Sulawesi and genotyped in the laboratory at the University of Idaho.

Kenya

- The first single location CFT will be harvested, yield estimated, and monitored for volunteer potatoes.
- Multilocation confined field trials will be conducted for the season B of 2022 and A of 2023. This will include obtaining authorizations from NBA and USAID, establishing the CFT, producing tuber seeds, cultivating the transgenic events and their comparators, and collecting the data for regulatory studies.
- Pathogen samples will be genotyped and depending on the diversity of the population, additional sampling will take place to complete the pathogen study.
- The candidate lead transgenic events for the 5th variety (Jalene) will be identified from the molecular and trait characterization.

Nigeria

- The first single location CFT will be harvested, yield estimated, and monitored for volunteer potatoes.

- A 'Brown Day' will be organized for local potato experts and other key stakeholders to view the yield difference between transgenic and non-transgenic potatoes under LB disease pressure (without fungicide protection).
- Multilocation confined field trials will be conducted for the rainy season in 2023. This will include obtaining authorizations from NBA and USAID, establishing the CFT, producing tuber seeds (including the lead transgenic event from Desiree which will be imported), cultivating the transgenic events and their comparators, and collecting the data for regulatory studies.
- Pathogen samples will be genotyped and depending on the diversity of the population, additional sampling will take place to complete the pathogen study.

3.2. Workstream 2: Regulatory Submission for General Release of the 3 R-gene LBR Potato

The objective of this workstream is to prepare and submit a regulatory dossier, obtain approval from the regulatory authorities, and build regulatory capacity for general release of biotech crops. Activities for Year 1 are outlined in the sections below.

3.2.1. Major Activities and Achievements

- Molecular characterization data was collected in the labs at MSU for the 2 Diamant events and the 3 Granola events and protocols/procedures/technology were established for capacity building and characterization of the 2nd Generation, including:
 - Single copy DNA characterization.
 - No large plasmid backbone sequence analysis.
 - Identify Insert location within event.
 - T-DNA flanking sequence analysis.
 - Development of event specific identity analysis.
 - T-DNA sequence characterization within event.
 - Chromosomal gene interruption characterization.
 - Analysis of chromosomal reading frames regarding T-DNA insertion.
 - Analysis of chromosomal insertion site in Non-Transgenic control.
- Virtual meetings were held by MSU with scientists from CIP, Samplix, MSU Research Technology Support Facility, Nanopore, Nanostring, Simplot Plant Sciences, U.S. Department of Agriculture (USDA), Food and Drug Administration (FDA) and the Van Andel Institute Genomics Core.
- A new highly efficient utilization of the X-Drop system was created by MSU and the Samplix team, which was utilized in the characterization of the T-DNA in each of the events.

- The report of the data for the analysis of one Diamant event, DIA-MSU-UB255, was sent to officials at the USDA and the FDA to confirm that this molecular data would be acceptable in a regulatory submission for deregulation in the United States.
- T-DNA insertion characterization of 8 transgenic events from the variety Jalene was done in the labs at CIP Nairobi using Nanodrop sequencing and X-Drop technology from Samplix. These transgenic events were selected for absence of significant portion of the backbone vector sequence, and with single copy of the *nptII* gene. The objective is to identify a couple of transgenic events with insertion meeting regulatory requirements.

3.2.2. Implementation Challenges

Bangladesh, Indonesia, Kenya, Nigeria

- Establishing protocols and procedures on molecular characterization data collection for the project's in-country scientists, balancing the latest, most efficient technology with procedures that are affordable and accessible to the scientists is a challenge.
- There is a significant amount of work and specialized skills and experience involved in collecting the described molecular characterization data for the events. This capacity is not easily transferred to the research partners in-country.
- A new X-Drop system technology offered by Samplix, a private company in Denmark, enables DNA enrichment of target areas of the genome, specifically T-DNA in this case. The data received from Samplix for the samples submitted was excellent, however, Samplix is no longer offering the service. To utilize the technology for 2nd Generation events, it will be necessary to identify an alternative service provider or utilize a different technology.

3.2.3. Expected Activities for the Upcoming Year

- Onboard a regulatory consultant/expert to assist with regulatory submission planning, reporting, and capacity building.
- Establish a plan for data collection, train the data collectors to ensure timely and quality data recording, and collect and analyze regulatory data from field trials.
- Continue molecular characterization and conduct protein characterization studies in the labs at MSU and CIP.
- Prepare regulatory reports for regulatory submissions.
- Hold regulatory submission planning meeting/workshops with in-country partners.
- Attend the 16th Symposium of the International Society for Biosafety Research (ISBR) in St. Louis.
- Complete and review all regulatory studies on Vic. I72 and prepare the dossier for regulatory submission in Kenya.

3.3. Workstream 3: Product Deployment Through Biotech Seed System and Stewardship

The objective of workstream 3 is to design and implement a plan for production and distribution of the 3 R-gene LBR potato to farmers. Activities for Year 1 are outlined in the sections below.

3.3.1. Major Activities and Achievements

- The process of hiring an agricultural economist that will oversee Workstream 3 project activities was initiated.
- Recruited a doctoral student in the Department of Agricultural, Food, and Resource Economics at MSU with extensive in-county work experience in Bangladesh to collect preliminary data on the potato value chain in Bangladesh.

3.3.2. Implementation Challenges

- The recruitment of an agricultural economist by CIP has presented challenge because of the small pool of specialists with knowledge in ex-ante socio-economic analyses. An offer was made, but the candidate will not join CIP until Quarter 2 of Year 2.

3.3.3. Expected Activities for the Upcoming Year

- Onboard agricultural economist to manage the activities in Workstream 3 (delayed from Year 1).
- Onboard socio-economic consultant/expert to assist with ex-ante assessment.
- Conduct ex-ante socio-economic assessment and market analysis for 3 R-gene LBR potato based on literature and secondary data collection.
- Host the first Potato Expert Elicitation workshop Kenya, then Bangladesh. The other countries will likely take place in Year 3.
- Socio-economic analyses will be drafted and finalized.

3.4. Workstream 4: Second Generation of Disease Resistant (DR) Potato

The objective of workstream 4 is to build the capacity of local scientists for the early development of disease resistance (DR) biotech potatoes and contribute to the product pipeline that will result in a second-generation disease resistant biotech potato. This report describes the development of Agrobacterium strains carrying DR constructs that will be shared with the project's in-country scientists for the development of 2nd generation disease-resistant potatoes. Activities for Year 1 are outlined in the sections below.

3.4.1. Major Activities and Achievements

- In Year 1, the project planned the 2nd Gen. DR biotech potato transformation construct.

- Research agreements were fully executed between MSU and The Sainsbury Lab (TSL)/2BLADES for the use of 3 late blight resistant genes, and the Potato virus Y resistance gene and the genes were obtained by MSU. A fully executed agreement between MSU and the USDA is in place for GAANTRY system research.
- The 2nd Gen. DR constructs with 3 late blight genes and the PVY resistance gene were developed at MSU using the GAANTRY system in 2 different strains of Agrobacterium to ensure transformation ability in different potato varieties, and the integrity of the constructs were confirmed using sequencing, PCR, and restriction digests.
- In-person meeting and several virtual meetings took place to plan training.
- Criteria were established for selecting second generation varieties and creating a product profile.
- Criteria were established for selecting one individual from each country to participate in the 1-month internships at the labs BecA in Nairobi, from Kenya and Nigeria in Quarter 1 of Year 2 and from Bangladesh and Indonesia in Quarter 2 of Year 2.
- Goals and an agenda were prepared for the 1-month internship in Year 2.

3.4.2. Implementation Challenges

- Obtaining the fully executed research agreements was challenging and time-consuming. In order to have the 2nd generation constructs completed in Year 1, MSU initiated the Intellectual Property Rights research and agreement process prior to the start of the award.
- Although the GAANTRY system is optimal for transformation with large constructs, it may not be accessible to project partners outside this project. In this case, we will train our partners on alternative systems for construct development in the interest of their future self-reliance.
- The gene plasmids obtained from TSL were sequenced to fill the gaps in the data provided by TSL. This helped to create the multi gene construct with greater accuracy but delayed the production of the new 2nd generation gene construct.

3.4.3. Expected Activities for the Upcoming Year

- Intellectual Property agreements will be fully executed with the in-country partner research organizations, so that the 2nd Gen. DR transformation Agrobacterium can be sent to the individual countries.
- The 2nd generation constructs developed will be sent to CIP for use during Year 2 training of our country partner scientists.
- In-country partner research organizations will select the potato variety to be transformed following key criteria (potential adoption, distinct from 1st generation, etc.) through local potato and project management consultation.
- Project country scientists will receive hands-on in-person training at CIP in Kenya.

- Country partners will conduct genetic transformation of their selected variety with the 2nd Gen gene construct.
- MSU and CIP will conduct back-up transformations with selected varieties using the 2nd Gen constructs.

3.5. Workstream 5: Communication and Advocacy

Workstream 5 aims to advance the knowledge of biotechnology and the benefits of GE LBR potato to potato value chain stakeholders to generate support and acceptance of the product along the entire value chain in the four countries where we work; and to effectively communicate benefits of biotechnology, GE potato and the project to potato value chain stakeholders globally to gain additional support for the technology. Activities for Year I are outlined in the sections below.

3.5.1. Major Activities and Achievements

Project level:

- Website created and updated (<https://www.canr.msu.edu/biotechpp>).
- Project fact sheet created and published.
- Social media accounts (Facebook and Twitter) created and maintained.
- Three quarterly newsletters published for FY2022. The first quarter newsletter was not distributed due to clearance not provided to announce project until second quarter of FY22 by USAID.

Bangladesh

- Service contract signed with FFB and Senior Manager for Communications and Advocacy was onboarded.
- Stakeholder mapping started but not completed.

Indonesia

- MoU has been signed with SEAMEO/Biotrop and service contract is in process. Service Contract was delayed with INDOBic due to reorganization of INDOBic into the SEAMEO/Biotrop organization.

Nigeria and Kenya

- There was no specific scheduled activity for workstream 5 for these countries in Year I.

3.5.2. Implementation Challenges

Bangladesh

- The delayed subaward agreement with BARI delayed outreach activities. The activities have been rescheduled for Year 2.

Indonesia

- Specific activities were delayed because of the delayed subaward agreement due to reorganization of government research agencies.
- Delayed agreement with INDOBic did not impact activities, due to delays in other workstreams.

3.5.3. Expected Activities for the Upcoming Year

Project level:

- Continue with digital strategy (social, web, newsletter).
- Write articles and news features as the project progresses.

Bangladesh

- Support the launch event, continue with stakeholder mapping and exercises, shoot videos and photos in the field, and plan BARI stakeholder activity.

Indonesia

- Finalize service contract with SEAMEO/Biotrop, execute risk communication workshops for the CFTs, conduct stakeholder mapping exercises.

Kenya

- Plan communications and advocacy event around CFT targeted to regulatory government stakeholders.

Nigeria

- Plan communications event around CFT.

3.6. Project Management

In year one, the program operations of the Global Biotech Potato Partnership focused on delivering the start-up technical deliverables and a suite of activities, achieving several milestones listed below.

3.6.1. Major Activities and Achievements

- Subaward agreements initiated with project partners.
- Establishment of Technical Advisory Board and first meeting held with all stakeholders.
- Submission of Annual Workplan, Branding Strategy and Marketing plan, and Monitoring, Evaluation, and Learning Plan.
- Project launch meeting in Kenya and Nigeria.
- Weekly meeting with the core management team.
- Monthly briefs with the lead countries.

- Monthly briefs with the AOR and Activity Manager.
- Establishment of Smartsheet as project management and MEL platform.
- Training of country partners on monitoring, evaluation, and learning.

3.6.2. Implementation Challenges

- Some project activities were delayed due to the processing of the subawards in Bangladesh and Indonesia.

3.6.3. Expected Activities for the Upcoming Year

- Finalize subaward agreements with Bangladesh and Indonesia.
- Project launch meetings in Bangladesh and Indonesia.
- Organize and hold next TAB meeting.
- Organize participation at the 16th Symposium of the International Society for Biosafety Research (ISBR).
- Continue meetings with partners and USAID.

IV. DATA MANAGEMENT UPDATE

The Data Management Plan (DMP) grounded in the project's Theory of Change was approved in March 2022 and is integrated into the project's M&E plan. All data, analytical methods, and findings generated by the project shall be packaged, shared and made available to the wider scientific and development community within USAID's Development Data Policy. The project will continue to adjust its DMP to adapt data collection or analysis to emerging needs.

V. LIST OF PUBLICATIONS AND PRESENTATIONS

Presentations

Magembe, E., Ghislain, M., Byarugaba, A. A., Barekye, A., Hui, L., Ali, T. & Suping, Z. (2022). Complete resistance to late blight disease of a biotech potato in sub-Saharan Africa, Paper Presentation Association of America 106th Annual Meeting, USA

Magembe, E., Ghislain, M., Byarugaba, A. A., & Bareka, A. (2022). Complete Resistance to Late Blight Disease of a Biotech Potato in Uganda. Paper presentation, 12th Triennial African Potato Association Conference, Malawi

Douches, D. S. (2022). Feed the Future Global Biotech Potato Partnership 2021-2026. Potato Expo - National Potato Council, USA

Douches, D. S., Hokanson, K., Ghislain, Wharton, P., Zarka, K. A., Magembe, E., Fierro, J., Payumo, J. & Marcy, J. (2022). Feed the Future Global Biotech Potato Partnership 2021-2026, Poster Presentation, Potato Expo - National Potato Council, USA

Douches, D. S., Hokanson, K., Ghislain, Wharton, P., Zarka, K. A., Magembe, E., Fierro, J., Payumo, J. & Marcy, J. (2022). Feed the Future Global Biotech Potato Partnership 2021-2026, Poster, Potato Association of America Annual Meeting, USA

Wharton, P. S. (2022). Efficacy of 3 R-gene late blight resistant potato cultivars in preventing infection by *Phytophthora infestans* in confined field trials in Indonesia. EuroBlight Workshop, Switzerland

Wharton, P.S., Sulastrini, I., Kusmana, Ambarwati, D., Santoso, T.J., Douches, D., and Hokanson, K.(2022) Efficacy of 3 R-gene late blight resistant potato cultivars in preventing infection by *Phytophthora infestans* in confined field trials in Indonesia, World Potato Congress, Ireland

VI. SUCCESS STORY

Project launch and confined field trials of late blight disease resistant potato in Kenya and Nigeria

The Feed the Future Global Biotech Potato Partnership held events in Kenya and Nigeria to launch the project which is working to commercialize a late blight disease resistant potato. In conjunction with the launch event, local national agricultural partners, Kenya Agricultural and Livestock Research Organization (KALRO) and National Root Crops Research Institute (NRCRI) Umudike Nigeria also announced the first in-country confined field trials of the potato which was developed through genetic engineering.

Potato is the third most important food crop worldwide. It is an essential crop that can play an integral role in achieving global food security. The potato produces more nutritious food, more quickly, on less land and in harsher climates than any other major crop. Disease, particularly late blight, is a main threat for potato farmers often resulting in total crop loss. Annually, over \$6.5 billion in global potato crop losses is attributed to late blight.

Technological advances have identified resistant genes from potato relatives that provide full control of late blight. Although these wild species are not suitable for cultivation, researchers have found that when stacking a series of three of these natural resistance genes and inserting them into popular farmer-preferred varieties, durable resistance to late blight can be achieved.

The launch event in Nigeria was held at NRCRI's Potato Research Sub-station in Plateau State. Over 50 stakeholders, including farmers, researchers, policymakers, and value chain actors attended the ceremony and guided tour of the confined field trial site. In Kenya, KALRO hosted over 35 participants at the launch event at their national headquarters in Nairobi. Providing additional support to the events were project partners the International Potato Center (CIP), the African Agriculture Technology Foundation (AATF), and Michigan State University (MSU) who leads the project.



Over 35 stakeholders gathered in Nairobi Kenya to launch the Feed the Future Global Biotech Potato Partnership project which works to bring a late blight disease resistant potato to smallholder farmers in Kenya, Nigeria, Indonesia, and Bangladesh. *Photo courtesy of Feed the Future Global Biotech Potato Partnership*

“This project will provide smallholder farmers in some of the most challenging regions for potato production a safe product to grow and market leading to increased potato yields and lower production costs for inputs,” explains [REDACTED], project director and director of the Plant Breeding Genetics and Biotechnology Graduate Program in the Department of Plant, Soil and Microbial Sciences in the College of Agriculture and Natural Resources at MSU. “A potato with durable host plant resistance to late blight will contribute to food security for developing countries throughout the world.”

[REDACTED] and his team have been working towards commercialization of the late blight disease resistant potato in Indonesia and Bangladesh since 2015. The Global Biotech Potato Partnership expands the scope of the research area to include Nigeria and Kenya and brings together MSU and CIP, who have both been working towards the common goal of late blight disease management.

[REDACTED], global leader of CIP's biotechnology research program, has been conducting parallel research on LBR potatoes in Africa over the last seven years. “By bringing together

MSU's research in Asia and ours in Africa, our research teams will collectively impact millions of smallholder farmers in food insecure areas," says [REDACTED], who leads activities in Kenya and Nigeria as the project's Deputy Director–Africa.



Participants tour the late blight resistant potato confined field trial location during the Feed the Future Global Biotech Potato Partnership launch event in Nigeria. *Photo courtesy of Feed the Future Global Biotech Potato Partnership*