
# Accelerating Crop Improvement Through Genome Editing

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Proposal

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**Note to readers:** Please use the hyperlinks throughout the proposal for definitions, abbreviations, partners, references, etc.

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**A list of acronyms used in this proposal can be found here.**

# Summary table

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|---|---|
| **Initiative name** | Accelerating Crop Improvement Through Genome Editing |
| **Primary Action Area** | Genetic Innovation |
| **Geographic scope** | ESA, LAC, SA, SEA, and WCA |
| **Budget** | US$25,451,526 |

# 1. General information

- **Full title**: Accelerating Crop Improvement Through Genome Editing
- **Short title**: Genome Editing
- **Primary Action Area**: Genetic Innovation
- **Lead and Co-lead**: Inez H Slamet-Loedin (Lead) and Marc Ghislain (Co-lead)
- **Initiative Design Team (IDT) members and affiliations**:

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# 2. Context

## 2.1 Challenge statement

Feeding the world population of 8.5 billion by 2030 will require improved sustainable production to increase yields of more nutritious and higher quality foods that are accessible for the world's most vulnerable populations. The growing demand for food will make the current production losses intolerable[1] with pressures on food security further compounded by predicted climate induced productivity decline[2] [3]. Conventional breeding has made significant advancements, demonstrating impressive levels of impact from genetic solutions for smallholders in developing countries[4]. Nevertheless, conventional breeding alone will not generate the step-change in yields required to meet future demand for high quality, nutritious food. A major technical drawback of conventional breeding is the inability to precisely select traits without including undesirable 'co-segregating' traits from donor lines (genetic linkage drag). Efforts to remove undesirable traits are never fully successful and require additional breeding cycles, prolonging the process, adding costs, and delaying benefit realization.

Genome editing (GEd) is a cost- and time-effective solution that can strategically complement conventional breeding[5]. GEd enables precise and predictable refinement of crop genomes[6] [7]. GEd can be done in elite breeding lines and commercial varieties, enabling quick and cheap delivery of essential traits to users[8]. GEd is being used in more than 40 crops across 25 countries, with six GEd crop varieties (soybean, canola, rice, maize, mushroom and camelina) approved for commercialization[9].

Despite the significant step-change in impact achievable through GEd and recent positive regulatory trends in many countries (including Argentina, Brazil, China, Colombia, Kenya, Nigeria, India, and the Philippines), debate and regulatory developments are ongoing. However, the discussion has shifted to a need for a sensible and pragmatic appreciation of benefits and risks, with a call to balance caution and innovation, recognizing that "governance must cope with a moving technical frontier"[10]. Statements from the G20 Agricultural Scientists (2021) and the European Commission (2021) affirmed the potential for New Genomic Techniques (NGT) to make valuable contributions to food security and environmental sustainability, concluding that "any further policy action should be aimed at reaping benefits from innovation while addressing concerns"[11]. Generally, within-species genetic changes using GEd are more readily accepted than transgenic innovations.

The Genome Editing Initiative (GEdI) takes a holistic and long-term view of growing future demand for GEd solutions as experience with the technology and social acceptance grows. Complementary innovations to support high standards of product stewardship, guide intellectual property management, facilitate licensing, encourage enabling societal and policy environments, and support delivery of GEd products to market have been included in Work Package 1 (WP1). Capacity building across NARS, SMEs and ARIs, collaborating partners in Work Package 2 (WP2), is designed to position these networks to use GEd more efficiently, effectively, and responsibly while building local innovation understanding and acceptance across socio-political landscapes. This will contextualize and promote equitable access and research spillovers, generating significant future benefits and minimizing future technological disadvantages[12] [13]. Work Package (WP3) has identified exogenous DNA-free GEd innovations with potential for transformative scales of impact that are in demand by partners who are enthusiastic for GEd enabled benefits (Annex 1 and Annex 2). As one prominent government official said at the planning consultation for this Initiative, "it will be important to harness the power of precision genetics, mainly genome editing, to deliver products that reduce hunger and poverty, and address actual needs of humanity" (Annex 3).

## 2.2 Measurable 3-year (end-of-Initiative) outcomes

The GEdI aims:

> **To deliver genetic solutions that are difficult to achieve with conventional breeding technologies, generating step-changes in the targeted Impact Areas.**

GEd will be used to overcome technical barriers to precise genetic changes, in a more timely and cost-effective manner.

**EIO 1. CGIAR, NARS and SMEs use a strategic approach for scaling GEd innovations, including frameworks to mitigate risks and harness opportunities**

Institutional innovation within CGIAR and across partners will embed the Eschborn Principles in holistic strategies, co-owned and co-implemented with local partners, to shepherd GEd opportunities from discovery through scaling and adoption. By 2025, joint decision-making frameworks are used by all CGIAR-NARS-SMEs GEd collaborations.

**EIO 2. NARS, end-users, policymakers are supported in using GEd as an option to address their agricultural development constraints and opportunities**

Partners who choose GEd solutions will be supported to effectively manage the GEd product lifecycle. By 2025, best practice guidelines and supporting materials that facilitate GEd choices are available to NARS and other critical actors.

**EIO 3. NARS, ARIs and SMEs co-develop and jointly use GEd lines in breeding programs to efficiently achieve step-change genetic gains for demand-driven traits**

By 2025, there will be significant predicted genetic gains in GEd products compared to conventional breeding counterfactuals, for the five initially prioritized crop/trait combinations.

**EIO 4. NARS, ARIs, SMEs and decision makers use GEd technology to incorporate the needs of women and youth in market-demanded products within agrifood systems**

GEdI will address the prevailing assumption that a market-oriented product profile will equitably address the needs of women and youth. GEd will enable multiple and complex combinations of traits that are otherwise ‘difficult to breed for’, ensuring gender targeted traits remain addressed. By 2025, GEdI will incorporate traits that benefit women and youth in market-demanded products.

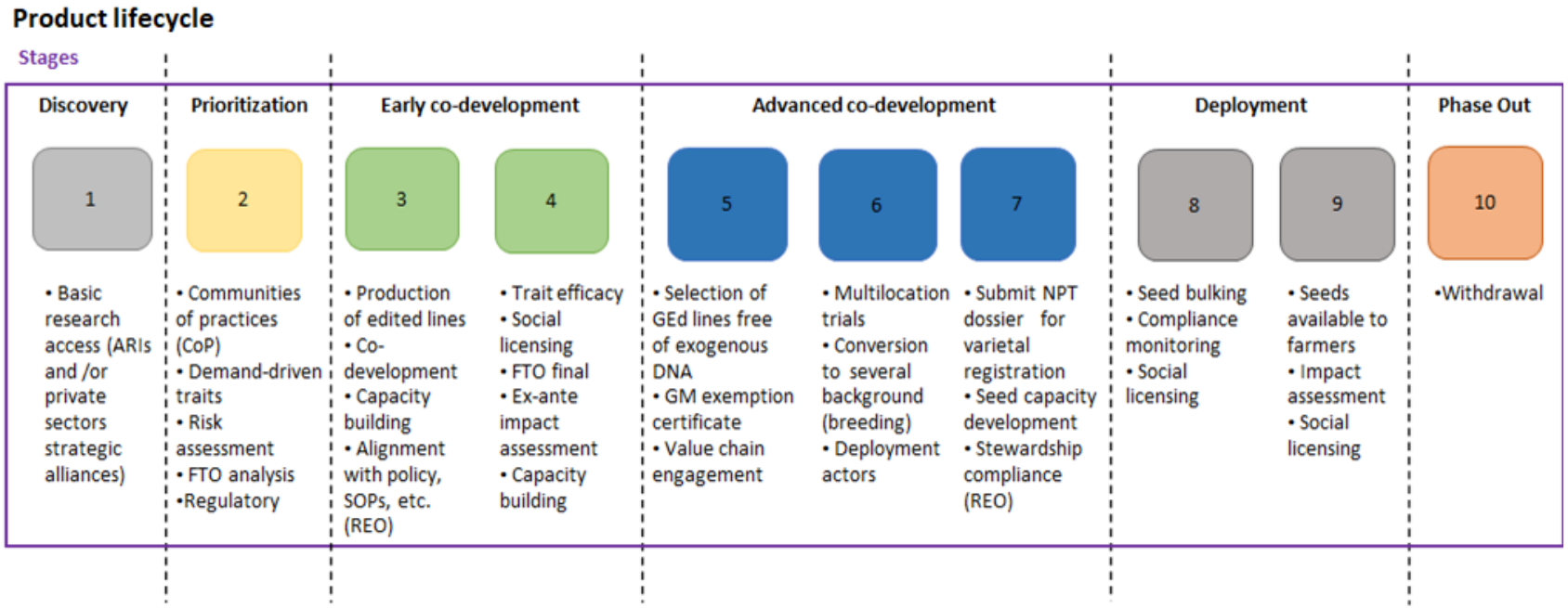



***Figure 1 GEd product lifecycle***

## 2.3 Learning from prior evaluations and impact assessments

In 2020, CGIAR entities collectively organized a large webinar series entitled 'One CGIAR Global Webinar Series on Genome Editing in Agriculture: Innovations for Sustainable Production and Food Systems'[14]. The robust discussion guided design of the GEdI. Key learnings include:

- **Proven technology:** GEd is a relatively new technology with only six products on the market in developed countries (i.e., in US, Japan), GEd is in use in more than 40 crops across 25 countries[15] [16]. These examples demonstrate the potential for GEd use and acceptance.
- **Readiness:** GEd technology has matured to today's widely used CRISPR tools[17] [18] [19]. Market-oriented GEd applications are clearly growing, and many are nearing commercialization[20] [21]. New priorities will emerge, so GEdI needs to remain responsive and adaptive.
- **Breeding efficiency:** In addition to trait enhancement by knocking out existing genes or editing them, GEd avoids costly genetic linkage drag and can increase genetic diversity in elite breeding lines without compromising highly valued traits[22]. Priorities will work with late-stage products and elite lines.
- **Balanced regulation:** In many countries, GEd end products with genetic changes that are undiscernible from those obtained by conventional breeding and natural variation, trigger non-transgenic regulatory positions[23]. The GEdI's scope is limited to exogenous DNA-free GEd products that are likely to gain GM regulation exemptions.
- **Socioeconomic-political conditions:** Public perception and political will can influence GEd innovations' impacts. Multi-disciplinary Innovation Packages are needed to support those partners seeking GEd innovations.
- **Social science capacity:** The synthesis of learning from a decade of CGIAR research identified the need to build social science capacity. This has been integrated and embedded into the design of GEd[24].

## 2.4 Priority-setting

Achieving GEdI's aim to deliver genetic improvements for traits that are 'difficult to breed for' using conventional breeding technologies (i.e., requires multi-year approaches and/or incur genetic and opportunity costs such as eliminating linkage drag) within a three-year initiative requires rigorous prioritization. It requires big lifts, strategic leveraging of CGIAR's past investments and impact driven solutions.

A desktop review of current CGIAR GEd research (28 genetic innovations) considered the research stage, exogenous DNA-free status, funding source and projected potential impacts. It also collated details on the local, regional, and global regulatory status and trends for target and spillover countries and regions.

The prioritization process (Annex 4) considered:

- Traits included in the existing breeding product profiles.
- Staple food crops for low-income people, including women and youth.
- Technical feasibility and development stage.
- Expected impact on one or more of the five Impact Areas of the CGIAR.
- Presence of an enabling socio-political landscape.

- Readiness for significant outcomes at the end of the Initiative.
- The spillover effect to new countries beyond the next three years.

The final priorities (Annex 5) span five food security crops and traits that can be significantly improved compared to existing varieties or breeding lines, address key constraints that have been difficult to resolve with conventional breeding, and are locally important, demand-driven targets. The prioritized Innovation Packages for the first year are:

- Resistance to BXW and Fusarium wilt in banana, targeted to Kenya, with spillover to Rwanda, and Uganda.
- Resistance to Cassava Bacterial Blight in cassava, targeted to Colombia and Nigeria, with spillover to Brazil.
- Resistance to late blight and PVY virus in potato, targeted to Kenya, with spillover to Bangladesh, Ethiopia, India, Nigeria, Rwanda, and Uganda.
- Climate resilience (fertilizer use efficiency, methane emission reduction and BPH resistance) in rice, targeted to Indonesia and the Philippines, with spillover to India and Nigeria.
- Resistance to leaf rust and powdery mildew in wheat, targeted to Kenya and India, with spillover to other African and South Asian countries.

More detailed analyses and consultations will be conducted to confirm the final priorities, identify future priorities and establish baseline metrics. Factors that will be more robustly analyzed include:

- Projected benefits for women and youth[25], climate change adaptation and mitigation, and environmental health.
- Intellectual property and FTO, including licensing status beyond research.
- Socio-political-economy and market environment related to genome editing.
- Partners' activities and resources available to leverage for mutual success.

Finally, close collaboration with all GI Initiatives will further refine current and future priorities (Annex 6). Research and expertise from Market Intelligence will help refine market-based prioritization of products. Coordination with Accelerated Breeding and Breeding Resources will create opportunities for including GEd products into breeding pipelines. A close working relationship with Genebanks will identify and access relevant genetic material. GEdI will work with Seed Equal to overcome social and seed network barriers, such as technology misconceptions, to ensure widespread uptake of final products. Collaboration with regionally integrated Initiatives (RII) through regional consultation will improve demand-articulation of the GEd innovations.

### 2.5 Comparative advantage

There is significant market failure when it comes to new GEd crop varieties for the developing world and disadvantages communities. In comparison, commercially released GEd varieties have been developed for wealthier markets that can afford varietal development and commercialization costs. This technological inequality is further exacerbated by the differences in crops and environmental conditions between wealthier markets and the priorities in this proposal, as there is limited shared product relevance and ability to leverage or transfer products. Targeted investment is needed to 'democratize' the benefits of science and overcome market failure.

By contrast, CGIAR's established network of strong collaborative partnerships, spanning ARIs, NARS and SMEs, brings the ability to support spillovers, with the transfer GEd technology and capacity. This will contribute to a narrowing of the technological and associated opportunity gaps between wealthier and resource-poor farmers[26].

CGIAR's not-for-profit, apolitical, and "honest technology broker" status affords it a strong competitive advantage to convene multi-institutional, multi-disciplinary partnerships with local credibility and knowledge to address social and institutional barriers to scaling[27].

CGIAR's comparative advantage is supported by its track record, including:

- An ambitious pipeline of GEd crops that is already under development[28], involving partnerships with NARS, ARIs and the private sector.
- Excellence Through Stewardship certification for CGIAR entities.
- Experience working with regulatory agencies in several target countries.
- Growing experience in approaches to social engagement to obtain social license.
- Global presence and state-of-the-art infrastructure to attract and retain talent (Annex 3).
- An established Program for Biosafety Systems that has successfully worked with government partners to provide regulatory policy assistance and capacity.
- Direct testimonial support for GEd by demand partners (Annex 2 and Annex 3).

### 2.6 Participatory design process

The social, policy and regulatory challenges associated with the release and widespread uptake of GEd products necessitates a joint approach to managing GEd products lifecycles. Partnerships must go beyond collaboration, to be genuinely demand-driven with co-ownership and co-implementation to maximize impacts for smallholders.

Through three regional events GEdI consulted stakeholders in Africa, Asia and Latin America to identify demand-driven priorities and key enabling issues needed to support GEd innovations under local conditions. A diversity of thought, gender, local relationships, and subject matter knowledge was gained by including:

- Market chain actors (e.g., seed companies, food processors, grain traders)
- Farmer organizations
- Consumer groups
- Agricultural, economics and other scientists
- Government and regulatory groups and individual experts
- Outreach and social acceptance professionals

Each consultation session commenced with an introduction to One CGIAR, the GI Action Area and a discussion of GEd opportunities and challenges. The following thematically grouped breakout sessions were used to gather insights:

- Research and technology developers
- Policy, regulatory and stewardship
- End-users

- Social license and acceptance

Key findings from the consultations endorsed the guiding principles, initial plans of work and further refined the design process for GEdI (Annex 3). The findings were invaluable for designing the Work Packages. The recommendations are summarized below:

- Develop a package of support for technology development, intellectual property rights (IPR), technology transfer and farmer release, extension, communications, and outreach (WP1).
- Ensure co-development of products with local partners with a cohesive, unified, comprehensive decision-making process (WP3).
- Capitalize and maintain global trust in CGIAR, while providing evidence-based, strategic outreach to build understanding of GEd options (WP2).
- Utilize skills in CGIAR to perform analytics that support priority setting, planning and product development as a package of evidence offered to stakeholders (WP1).
- Develop a common approach to regulation that is evidence- and science-based (WP1).
- Routinely address IPR and licensing early in product development to secure pathways for commercialization of, and equitable access to, GEd products (WP1).

Following the regional consultation, additional feedback was received from several funder representatives.

Letters of support from numerous potential partners and stakeholders (NARS, key ministries, and regulatory leads) testifying to the demand from target countries have been received (Annex 2). The letters signal a substantial foundation for market and social acceptance and demonstrate that identified priorities are aligned with local and regional priorities. Furthermore, these letters confirm demand, show commitment to research co-development, and indicate readiness for GEd technologies.

The consultative and participatory approaches used in initiative design are the first step in a continuing and evolving process. Throughout all stages of GEdI consultation with diverse stakeholders and other GI Initiatives will continue to inform implementation. This will guide course corrections to ensure that GEdI is responsive, flexible, and sensitive to locally changing context and policy climates, market realities, the evolving science, and the needs of our ultimate beneficiaries.

### 2.7 Projection of benefits

The projections below transparently estimate reasonable orders of magnitude for effects which could arise as a result of the impact pathways identified set out in the Initiative's theory of change (TOC). Initiatives *contribute* to these impact pathways, along with other partners and stakeholders.

For each Impact Area, projections consider breadth (numbers reached), depth (expected intensity of effect per unit) and probability (a qualitative judgement reflecting the overall degree of certainty or uncertainty that the impact pathway will lead to the projected order of magnitude of impact).

Projections will be updated during delivery to help inform iterative, evidence-driven, dynamic management by GEdI to manage its potential contribution to impacts. Projected benefits are not delivery targets, as impacts are beyond CGIAR's sphere of control or influence.

The in-depth projections to be made during the GEdI's implementation will use economic impact assessment studies, considering factors such as markets, technology delivery, adoption, R&D

delays, and regulatory compliance. CGIAR tools to implement in-depth projections include DREAMpy, IMPACT, and NetMap. These will be augmented by other state-of-the-art analytical tools.

The impacts of GEd technology materialize when improved varieties are adopted by smallholder farmers, including women and youth. Success will build on all six Initiatives in the GI Action Area, which jointly contribute to timely and efficient development, release, dissemination, and adoption of improved, in-demand varieties through common impact pathways (Figure 2). In addition to producing and delivering better quality seed to target beneficiaries in priority market segments, the research strategy and activities aim to modernize and transform the genetic innovation system. The projected benefits of the five prioritized GEd innovations are aggregated projected benefits of this Initiative, working in collaboration with other GI Initiatives, each contributing at different stages along the research to adoption pathway.

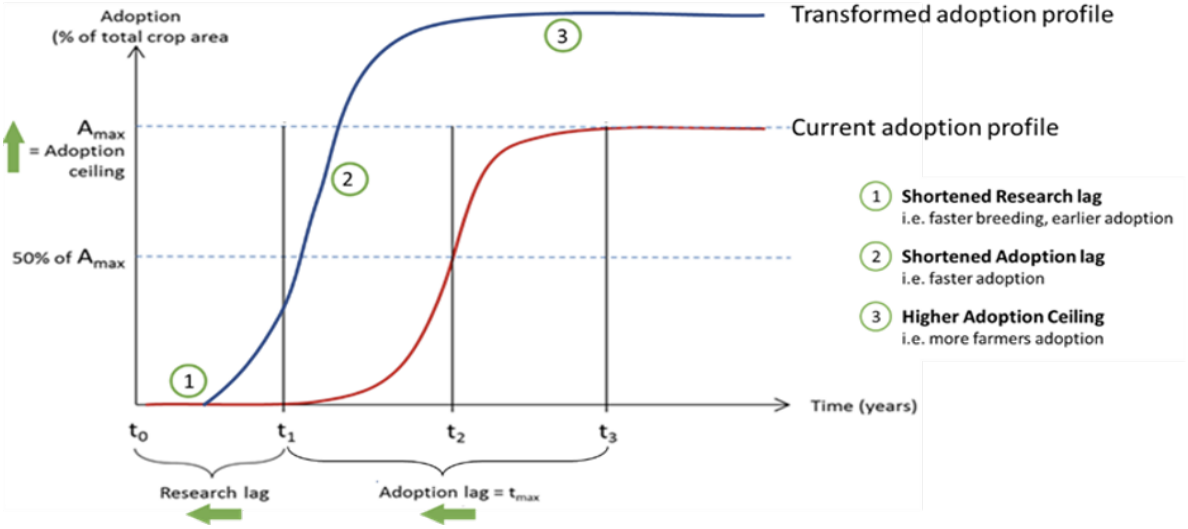



***Figure 2. Adoption profile impact of GI Initiatives***

Market Intelligence together with policy, economic and regulatory analysis, technical support, and capacity development (WP1), can enhance the enabling environment for innovations. This can reduce adoption lag and increase adoption as new varieties are targeted to specific market segments and social, political, and regulatory barriers are overcome. The result will be a more complete replacement of existing varieties and accelerated varietal turnover to improve farmers' yield and resilience, generating quicker impacts.

Investment in gene banks will decrease the research lag by making germplasm available to breeding programs, reducing the search time and cost of developing germplasm with key traits. In addition, potentially game-changing traits are identified, preserved, and accessible, contributing to future resilience and biodiversity.

Modernized strategies and approaches will accelerate breeding (Accelerated Breeding and Breeding Resources), thereby reducing the research lag and generating multiplier effects on the benefits from breeding and seed systems. Efficient seed delivery (Seed Equal) will accelerate and increase adoption as products reach targeted, disadvantaged farmers more quickly. Moreover, enabling access to high-quality seed and planting material ensures that the potential of genetic innovations is realized in farmers' fields.

In the package of GI AA Initiatives, the GEdI will contribute to impacts by:

- Increasing likelihood of research success (probability) by precise changes, facilitating the use of superior forms of genes (alleles) to enhance traits in ways that are difficult to achieve by conventional breeding.
- Reducing research lag, more quickly circumventing disadvantage (breadth) and cost by reducing the number of breeding cycles (time to product).
- Increasing genetic gain in the materials produced (depth).
- Increasing the number of potential beneficiaries (breadth) when complex, multi-trait varieties are produced (e.g., incorporating traits for women and youth in market-demanded varieties) in collaboration with Accelerated Breeding and Breeding Resources.

Projections of expected benefits of the Initiative's priority innovations (Table 2) are the product of analysis based on available data in the literature and expert consultations. Data collected included those for key parameters and assumptions comprising adoption ceiling rates, research and adoption time profile, household and poverty characteristics in target countries, and area domains to estimate impact indicators for GEd technologies adoption at a cut-off date of 2030. Annex 7 describes the approach to derive these estimates.

***Table 2. Projection of Benefits***

| **Breadth** | **Depth** | **Probability** |
|---|---|---|
| **Impact Area:** Nutrition, health & food security<br>**Impact Indicator:** # people benefiting from relevant GEd innovations | | |
| • *Pest/Disease resistant banana*: 44,000 ha and 533,000 people in Kenya, Rwanda, and Uganda<br>• *Cassava Bacterial Blight (CBB) resistant cassava*: 80,000 ha and 452,000 people in Brazil, Colombia, and Nigeria<br>• *Disease and viral (LB, PVY) resistant potato*: 77,000 ha and 864,000 people in Bangladesh, Ethiopia, India, Kenya, Nigeria, Rwanda, and Uganda<br>• *Climate change mitigation (Nitrogen Use Efficiency) and Brown Planthopper resistant rice:* 15.5 million ha and 91 million people in India, Indonesia, Nigeria, and Philippines<br>• *Disease resistant wheat*: 659,000 ha and 1.5 million people in Kenya and India. Potential for expansion in Africa and Southern Asia of 1.9 million ha and 3.2 million beneficiaries. | Significant:<br>10% permanent impact on income | High certainty:<br>50-80% expectation of achieving these impacts by 2030, at this point |
| TOTAL: > 96 million people (> 16.5 million hectares) | | |
| **Impact Area:** Poverty reduction, livelihoods & job<br>**Impact Indicator:** # poor people benefiting from relevant GEd innovations | | |
| • *Pest/Disease resistant banana:* 44,000 ha and 140,000 poor people in Kenya, Rwanda, and Uganda<br>• *Bacterial Blight (BB) resistant cassava:* 77,000 ha and 181,000 poor people in Brazil, Colombia, and Nigeria | Significant<br>10% permanent impact on income | High certainty:<br>50-80% expectation of achieving these |

| | | |
|---|---|---|
| • *Disease and viral (LB, PVY) resistant potato:* 205,000 ha and 678,000 poor people in Bangladesh, Ethiopia, India, Kenya, Nigeria, Rwanda, and Uganda<br>• *Climate change mitigation (Nitrogen Use Efficiency) and Brown Planthopper resistant rice:* 15.5 million ha and 16 million poor people in India, Indonesia, Nigeria, and Philippines<br>• *Disease resistant wheat:* 659,000 ha and 0.33 million poor people in Kenya and India. Potential expansion in Africa and Southern Asia projected benefit of 1.9 million ha and 1 million beneficiaries. | | impacts by 2030, at this point |
| TOTAL: > 96 million people (>18 million poor people) | | |
| **Impact Area:** Gender equality, youth & social inclusion<br>**Impact Indicator:** # women benefiting from relevant GEd innovations | | |
| • *Pest/Disease resistant banana:* 182,000 women producers in Kenya, Rwanda, and Uganda. Represents >44,000 hectares. | Transformative:<br>Underlying process supports greater gender equality | High certainty:<br>50-80% expectation of achieving these impacts by 2030, at this point |
| TOTAL: > 34.7 million women farmers (>18 million poor farmers) | | |
| **Impact Area:** Climate adaptation & mitigation<br>**Impact Indicator:** # people benefiting from climate adapted GEd innovations | | |
| • *Climate change mitigation (Nitrogen Use Efficiency) and Brown Plant hopper resistant rice:* 15.5 million ha and 91 million people (16.8 million poor people) in India, Indonesia, Nigeria, and Philippines | Significant:<br>10% permanent impact on income | High certainty:<br>50-80% expectation of achieving these impacts by 2030, at this point |
| TOTAL: 91 million people (>18 million poor people) | | |
| **Impact Area:** Environmental health & biodiversity<br>**Impact Indicator:** #ha under improved management | | |
| Aggregate disease resistance and climate-resilient traits: 16.5 million ha | Significant:<br>Improved pest and disease management delivers biodiversity gains | Very high certainty:<br>50–80% expectation of achieving these impacts by 2030, at this point in the design process |
| TOTAL: >16.5 million hectares | | |

### 1. Nutrition, health, and food security

**# People benefiting from relevant GEd innovations:**

All five prioritized GEd innovations are disease- or pest-resistant varieties. GEd technologies will enhance food security for 96 million people by addressing pests and diseases on more than 16.5 million hectares, resulting in reduced crop losses, increased food production and consumption, and sale of surplus production. The number of beneficiaries was projected using crop/country specific adoption profiles based on expert opinions and experience, secondary data on production areas, and other available data such as average household size, and crop area per household.

Although there is not an explicit GEd innovation focused exclusively on nutritional and health traits, we foresee an increase in such traits with advances in GEd techniques. Addressing nutritional and health deficiencies is a priority and presents many opportunities for the GEdI to contribute to reducing the burdens from vitamin and micro-nutrient deficiencies, (see Global Burden of Disease Study of 2015[29]) including vitamin A, iron, and zinc, among others. These affect children, lactating mothers and other vulnerable groups in Africa, South Asia, and elsewhere, negatively affecting the nutrition and health of billions of people.

### 2. Poverty reduction, livelihoods, and jobs

**# Poor people benefiting from relevant GEd innovations:**

More than 18 million poor people are projected to benefit from the adoption of GEd technologies on over 16.5 million hectares. This was estimated by multiplying the projected number of adopters by 2030 in each country by the poverty headcount ratio at national poverty lines in the World Bank Development Indicators and other sources for the most recent year available. More than 2 billion people globally depend on smallholder farms for their livelihoods. These farms are usually more vulnerable to crop loss caused by pests and diseases, as their farmers often lack training or access to management practices and agrochemicals to control those threats.

An example of in-depth projection of economic benefits is available for MLN resistant maize hybrids. This project is funded outside of GEdI. The average annual benefits from the adoption of MLN resistant hybrids amount to US$33 million in Kenya alone and US$59 million for all adopting countries (Annex 7). The internal rate of return for all countries is 85% but varies between 80-226% across countries. The rate of discount used in the estimates is 10%, which means this is a worthwhile investment. Cost savings in the development and delivery of GEd innovations will increase the internal rate of return significantly. Estimated benefits are a fraction of maximum expected benefits because 2030 is early in the adoption curves of these innovations.

### 3. Gender equality, youth, and social inclusion

**# Women benefiting from relevant GEd innovations:**

One example of potential GEd innovations benefiting women is GEd banana with disease resistance. Rarely available gender disaggregated data shows that the share of women banana farmers varies from 24% in Uganda to 37% in Nigeria but could be as high as 90% in Kenya. As a transformative impact, we project that 182,000 women farmers will benefit from adoption of a GEd pest and disease resistant banana over more than 44,000 hectares. Women will benefit from GEd technologies due to increased income, food availability, and health and nutrition benefits. We followed the estimation steps outlined in Annex 7 and then computed the share of women producers among all adopters. Our estimates do not consider women and youth labor contributions beyond benefiting as crop producers.

When addressing gender in benefit projections, it is critical to use disaggregated gender data and not to assume that women constitute 50% of farmers (difficult to verify in the absence of available

gender disaggregated data), or the characterization of some crops as a "woman's" crop. From a policy standpoint it is more important to identify the conditions that prevent women farmers from capturing at least as many benefits as male farmers. This includes an examination of access to credit, information, land titles, and technology (Annex 7).

### 4. Climate adaptation and mitigation

**# People benefiting from climate-adapted GEd innovations:**

An enabling environment supported by socio-economic and political economy analysis will facilitate more timely and predictable deployment of GEd products, many of which are "climate and environment friendly," with lower greenhouse gas emissions and expected higher productivity. An environmentally friendly rice innovation is expected to have better nitrogen mobilization coupled with brown planthopper resistance that may contribute to reducing greenhouse gas emissions by 50%. We project that 96 million people will benefit from climate change mitigation of GEd rice on >16.5 million hectares. Our estimations follow the proposed adoption profile (rates and timelines). During implementation, we will add enhanced climate change impact indicators measuring GHG drivers and potential adaptation/mitigation impacts (e.g., reductions in methane and $CO_2$ emissions). GEd techniques can help farmers with climate change adaptation by developing climate-resilient crop varieties. Some experts have suggested that GEd technologies could shorten the product development cycle by 3–5 years (personal communication), which could significantly accelerate the development of climate-resilient, locally adapted varieties with other beneficial characteristics.

### 5. Environmental health and biodiversity

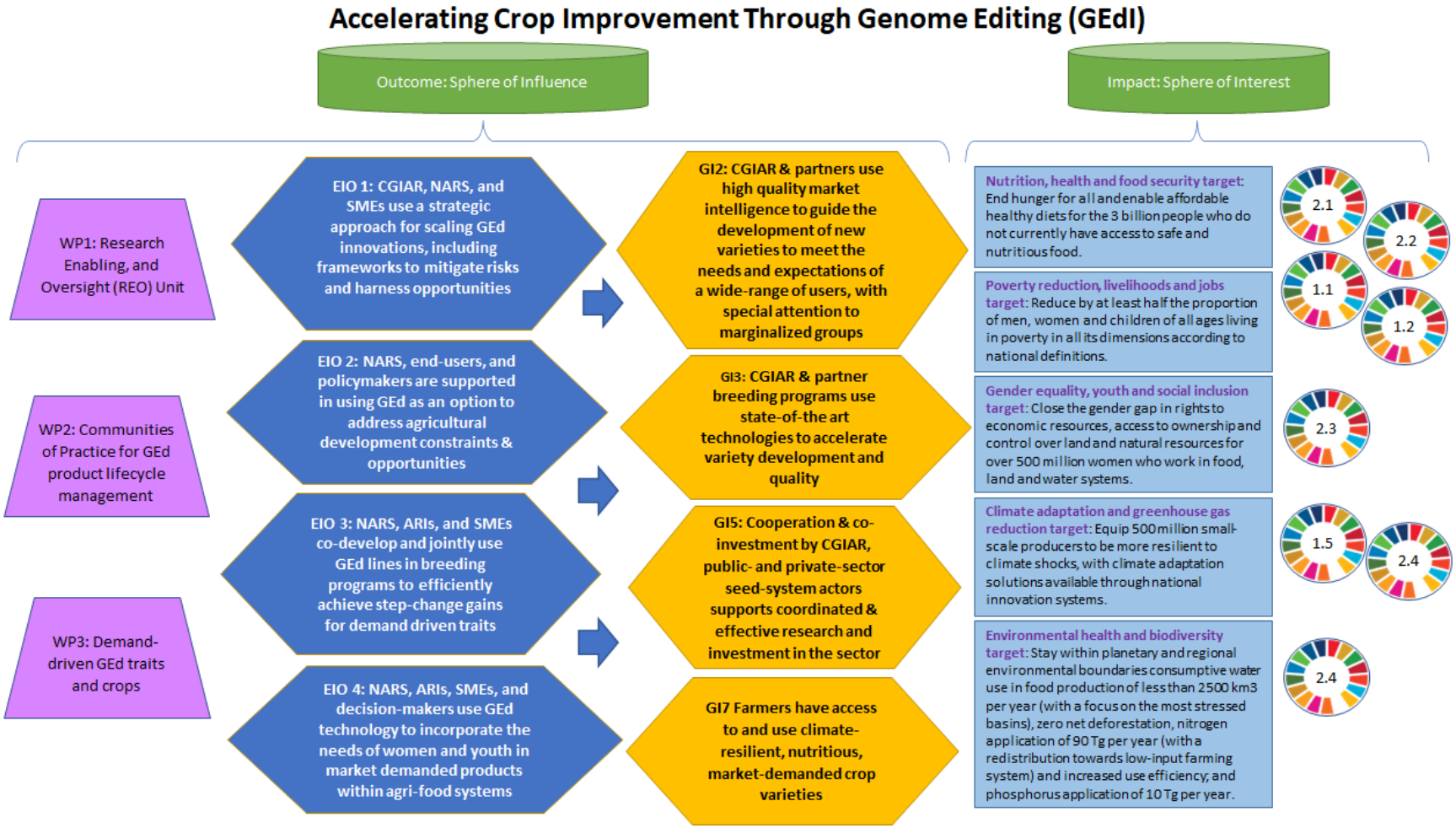
**# Hectares under improved management:**

Goal focused GEd innovations can facilitate improved integrated pest management (IPM) by reducing or better targeting applications of some agrochemicals to control pests or diseases. An example is the late blight (LB) and virus resistant potato and the rust and powdery mildew resistant wheat, which can be grown with reduced or without fungicides. (Fungicides are a large portion of agrochemical imports by potato-producing countries[30].) We project more than 16.5 million hectares adoption with GEd technologies that incorporate traits for disease resistance and climate change resiliency. Such GEd varieties facilitates better management practices and improved use of agrochemical inputs to mitigate impacts of agriculture on biodiversity and the environment. Focused environmental, health and biodiversity indicators will be estimated during implementation[31]. Pest and disease resistance and more rationalized use of chemical nutrients will favorably impact biodiversity, land, and water resources. Overall, the depth of GEd impact is expected to be significant, as has been documented for other gene-based innovations[32].

# 3. Research plans and associated theories of change (TOC)

## 3.1 Full Initiative TOC

### 3.1.1 Full Initiative TOC diagram



### 3.1.2 Full Initiative TOC narrative

GEdI aims “to deliver genetic solutions that are difficult to achieve with conventional breeding technologies, generating a step-change in the targeted Impact Areas”, i.e. SDGs (1, 2, 3, 5, 10, 12, 13). Impact will only occur when GEd innovations and the enabling social and governance policies and systems are in place, supporting varieties developed from GEd breeding lines to progress to market and use. Work Packages 1 and 2 will foster enabling environments, while Work Package 3 will develop GEd innovations.

WP1 will establish a Research Enabling and Oversight (REO) Unit to provide strategic leadership on the current and future use of GEd, spanning the product lifecycle. The REO Unit will monitor global needs, maintain consultation with diverse stakeholders including regulators and seed systems, and undertake impact projections to inform rigorous Eschborn-aligned prioritization. WP1 will work alongside Market Intelligence and Accelerated Breeding to identify GEd opportunities that complement GI’s portfolio of conventional breeding. WP1 will establish a framework for successful GEd investment that can accommodate future GEd opportunities. These activities will achieve the EIO ‘CGIAR, NARS and SMEs use a strategic approach for scaling GEd innovations, including frameworks to mitigate risks and harness opportunities’, and contribute to the GI outcomes ‘CGIAR & partners use high quality market intelligence to guide the development of new varieties to meet the needs and expectations of a wide range of users, with special attention to marginalized groups’ and ‘cooperation & co-investment by CGIAR, public- and private-sector seed-system actors supports coordinated & effective research and investment in the sector’.

WP2 will form expert-supported, gender and age diverse, cross organization Communities of Practice (COP) covering technical, social and policy aspects of the GEd product cycle. Learning and experience will be shared to co-develop best practice guidelines and supporting resources, building capacity of CGIAR’s partnered breeding network and achieving the EIO ‘NARS, end-users and policymakers are supported in using GEd as an option to address agricultural development constraints & opportunities’, and contributing to the GI outcome ‘CGIAR & partner breeding programs use state-of-the-art technologies to accelerate variety development and quality’.

WP3 will progress identified priorities, to achieve both EIOs ‘NARS, ARIs and SMEs co-develop and jointly use GEd lines in breeding programs to efficiently achieve step-change gains for demand driven traits’ and 'NARS, ARIs, SMEs and decision-makers use GEd technology to incorporate the needs of women and youth in market-demanded products within agrifood systems’, significantly contributing to the GI outcome ‘Farmers have access to and use climate-resilient, nutritious, market-demanded crop varieties.’

GEdI’s logic assumes that:

- Technical and non-technical innovations are needed to progress GEd innovations to market.
- GEdI priorities will complement conventional breeding priorities, forming a unified portfolio.
- There are sufficient demand partners for GEd innovations, and they will be more effective if supported to develop and implement strategies to progress GEd innovations to market.
- Partnering organizations will collaborate on common challenges to co-develop tools and resources for broader use.
- GEd breeding lines will be accepted into conventional breeding programs.

- Increased pest and disease resistance will increase crop yields, improving food security and nutrition and reducing poverty.
- Increased pest and disease resistance will support better IPM with improvements for environmental health and biodiversity.
- Improved translocation of nitrogen will reduce the need for fertilizers and other trait improvements, reducing methane greenhouse gas emissions.

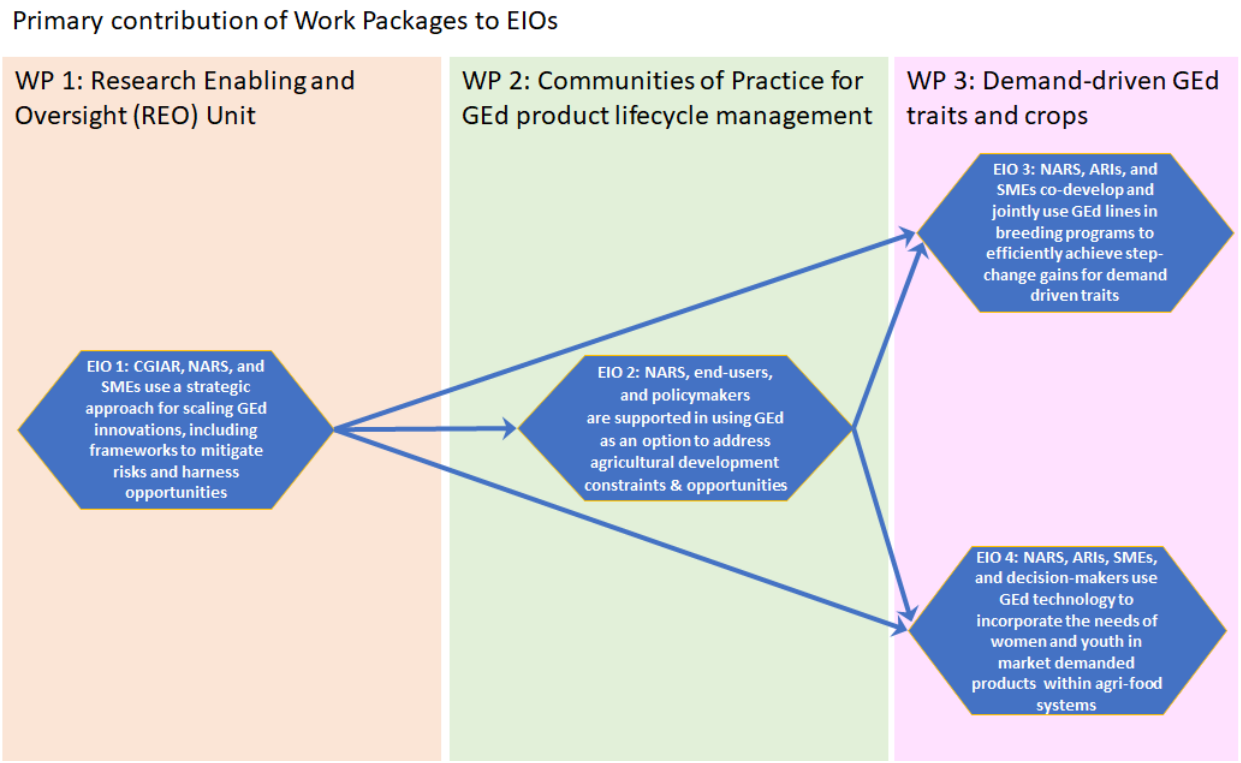



***Figure 3 Primary contribution of Work Packages to EIO***

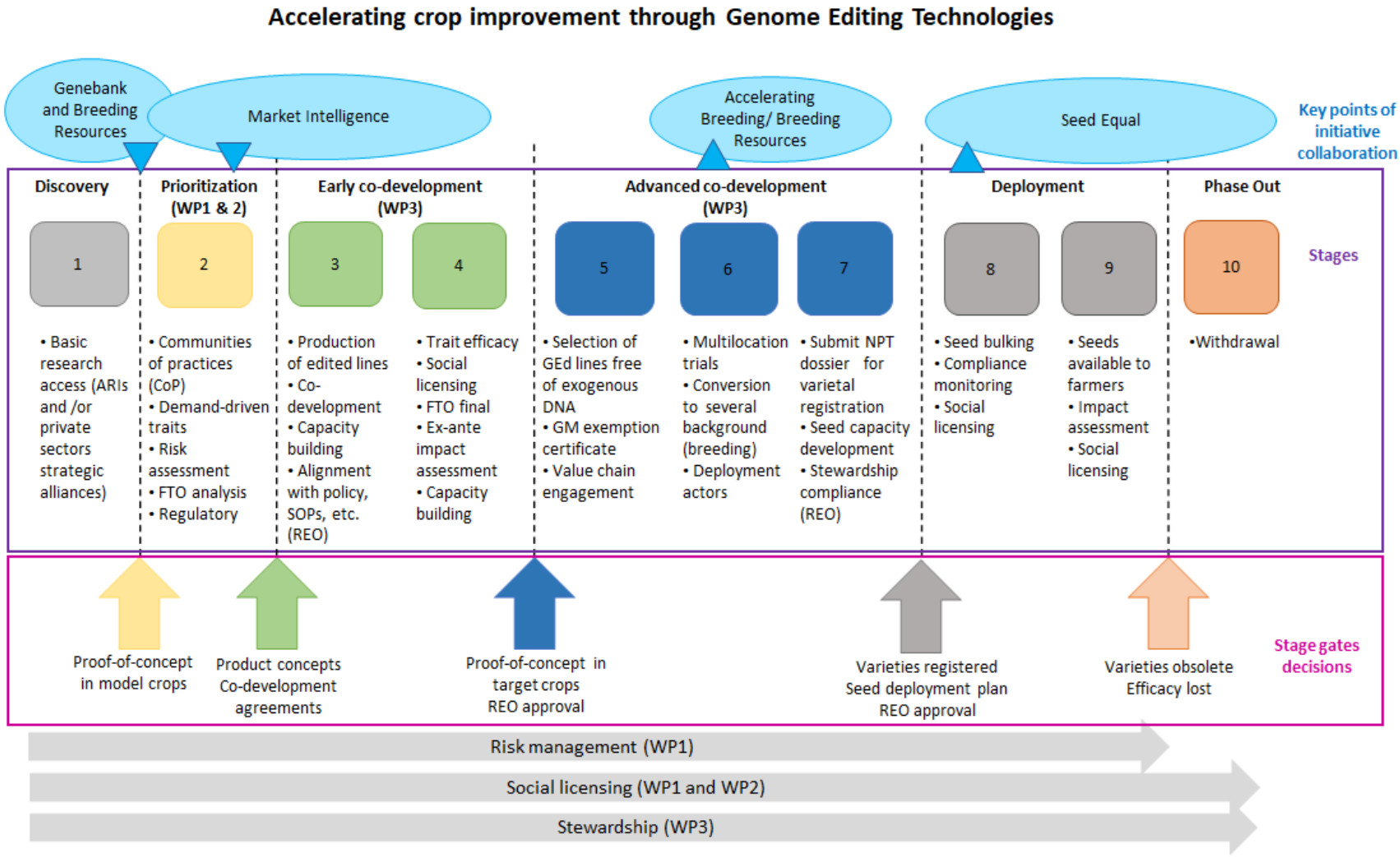
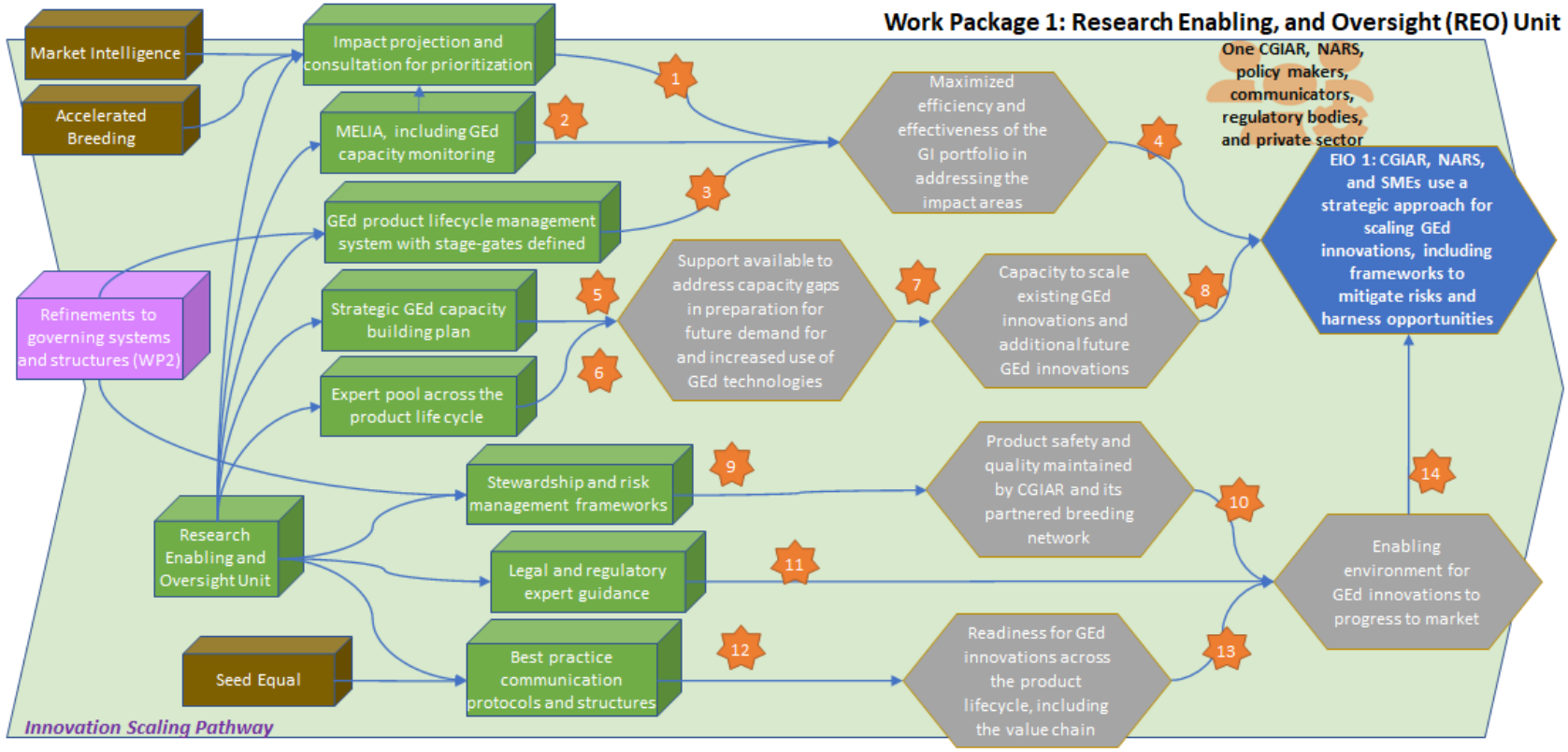


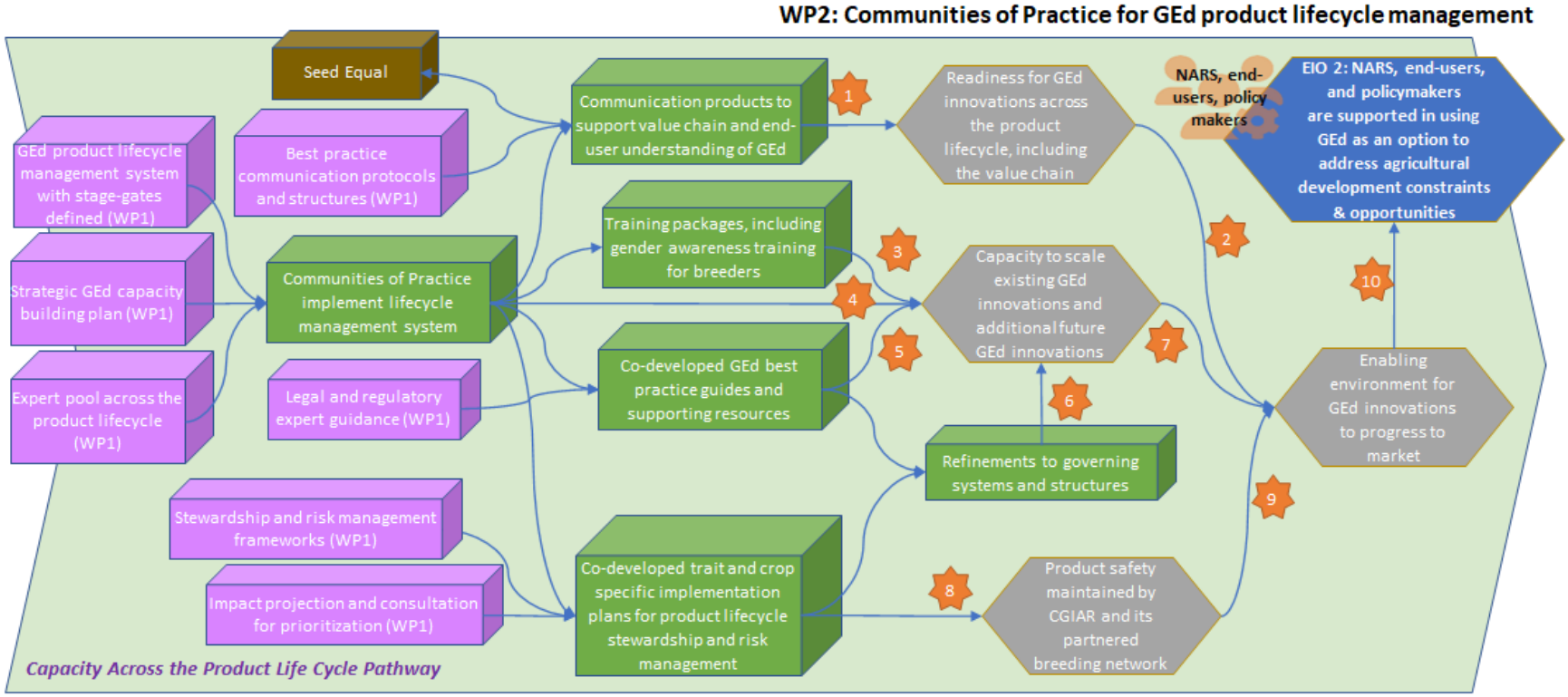

***Figure 4 Overview of Work Packages and Initiative collaborations across the product lifecycle***

## 3.2 Work Package TOCs

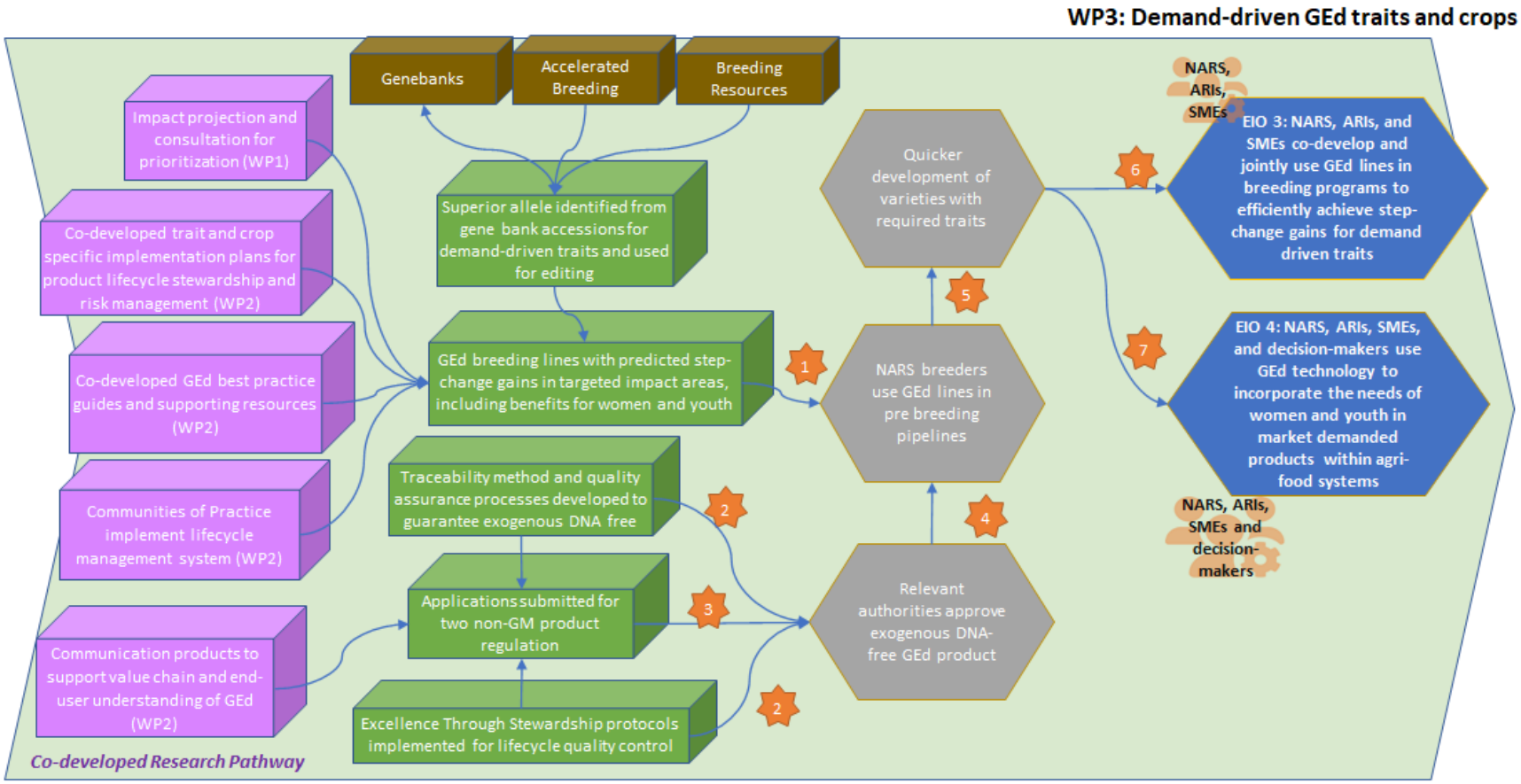
### 3.2.1 Work Package TOC diagrams




| Assumptions | | | |
|---|---|---|---|
| 1 | Increased prioritization rigor, that includes impact projections, will maximise the efficiency and effectiveness of GEd investments. GEdI priorities will complement Market Intelligence and Accelerated Breeding | 8 | Increased capacity is needed to scale GEd innovations |
| 2 | MELIA will inform adjustments to the GEdI priorities, ensuring ongoing maximized efficiency and effectiveness | 9 | Stewardship and risk management frameworks will deliver improved product safety and quality |
| 3 | A management system will embed strategic decision-making and improve efficiency and effectiveness | 10 | Product safety will increase social acceptance and contribute to an enabling environment for scaling GEd innovations to market |
| 4 | Efficiency, effectiveness and risk and opportunity management are part of a strategic approach to scaling | 11 | Legal and regulatory expertise can be applied to create an enabling environment |
| 5 | There are currently capacity gaps in the use of GEd | 12 | Communication will improve understanding, acceptance and preparedness for GEd innovations |
| 6 | There are available experts across the product life cycle | 13 | Preparedness and user readiness will positively contribute to an enabling environment |
| 7 | The increase in capacity is sufficient for taking on more GEd projects, as demand for GEd grows. | 14 | An enabling environment is required for scaling GEd innovations |




| Assumptions | |
|---|---|
| 1 | Communication will increase social acceptance of GEd, creating a readiness and demand to use GEd innovations |
| 2 | User readiness is required as part of an enabling environment |
| 3 | Training across the product life cycle will increase capacity to scale existing GEd and create a legacy of capacity that can be used for future GEd projects. It will also create pull through of gender awareness. |
| 4 | There is sufficient experience in each stage of the product life cycle to create Communities of Practice. The sharing of learning and experience increases the overall capacity of the breeding network. |
| 5 | Co-developed GEd best practice guides and resources can be applied in different contexts, increasing overall capacity of the breeding network |
| 6 | During implementation, improvements will be identified and shared with WP1 to refine the frameworks and guidance available for future GEd projects |
| 7 | The capacity gained will positively foster an enabling environment, with the required social, political and regulatory support for release and use of GEd products |
| 8 | The strategies are effectively implemented to manage risks, there are no unmitigated risks and product safety is maintained |
| 9 | Demonstrated product safety will influence decision-makers and contribute to increased social and political acceptance of GEd, as part of an enabling environment |
| 10 | An enabling environment is needed for NARS, end-users and policy makers to successfully implement their choice to use GEd solutions. |




| Assumptions | |
|---|---|
| 1 | NARs have the capacity to appropriately use and manage GEd breeding lines |
| 2 | Certification will require confidence in the methods used to safeguard non-transgenic status of GEd products |
| 3 | Provision of data and resources can help certifiers to approve GEd breeding lines, in a timely manner |
| 4 | Certification will encourage use of GEd breeding lines in conventional breeding. |
| 5 | GEd can make precise changes to the genome, avoid time consuming back crossing and develop breeding lines with the desired traits quicker |
| 6 | The use of GEd parentals will increase the speed at which step-changes can be achieved in demand driven traits |
| 7 | GEd parentals are used in conventional breeding lines and multi-trait products are released that include that support women and youth |

### 3.2.2 Work Package research plans and TOCs

#### Work Package 1

| *Work Package title* | **Research Enabling and Oversight (REO) Unit** |
|---|---|
| *Work Package main focus* | Work Package 1 (WP1) describes a new centralized, coordinated governance and oversight platform, the Research Enabling and Oversight (REO) Unit. The REO Unit will provide strategic direction to WP2 and WP3, and actively engage across Initiatives and other investments within One CGIAR. This unit does not exist in the current One CGIAR structure but is needed to support GEdI and future GEd research. |
| *Work Package geographic scope (Global/Region/Country)* | Global |

**The science**

GEd, like most disruptive technologies, faces questions on product safety, risks, intellectual property and freedom to operate. In addition, the social, political and regulatory landscape poses potential barriers for the equitable use of GEd technologies by NARS and SMEs. To address concerns and support NARS and SMEs who wish to use GEd technologies to improve crops, WP1 will provide coordinated and strategic oversight across the product life cycle. Interaction with CGIAR system and Center-level management and governance structures will be needed to empower WP1 to achieve its envisioned role and impacts.

WP1 will convene a multi-disciplinary team of researchers and professionals with skills to manage, enable, and oversee the efficient and impactful use of GEd technology. The REO will be a structural shift in CGIAR business operations to centrally manage GEd research investments using a new institutional platform with stewardship and risk management frameworks, MELIA and prioritization, and governance structures for accountability and compliance. The platform created will initially focus on the GEdI's five prioritized innovations, before the REO will seek additional investment for the next GEd priorities and provide management oversight services to other GEd projects within One CGIAR and its partners.

The REO will identify and set directions for WP2 and WP3 with active consultation across CGIAR entities and demand partners. These actions will be informed by detailed impact projections and expert advice. REO will also coordinate resources for capacity building in the Communities of Practice (WP2).

| **Research Question** | **Scientific methods or activities** | **Outputs** |
|---|---|---|
| Can a centrally managed Research Enabling and Oversight unit (REO) create enabling structures and opportunities to use GEd at scale (current and future projects)? | Institutional innovation<br>Consultation with demand partners<br>Coordination within One CGIAR<br>Innovation Scaling Analysis | • Research Enabling and Oversight Unit |

| | | |
|---|---|---|
| Will the current priorities need to change in response to changing global, regulatory or other changes? | DREAMpy, IMPACT, and NetMap<br>Consultation with demand partners | • Impact projection and consultation for prioritization<br>• MELIA, including GEd capacity monitoring |
| What are the critical capacity gaps across the product lifecycle and partnering organizations? | Multi-stakeholder capacity audit<br>Engage experts to form a centralized pool of resources to support the Communities of Practice (WP2) | • Strategic GEd capacity building plan<br>• Expert pool across the product lifecycle |
| How can NARS, SMEs and policymakers be supported to implement GEd technologies in local policy environments? | Review existing requirements<br>Engage legal and regulatory experts<br>Design stewardship and risk management frameworks | • Stewardship and risk management frameworks<br>• Legal and regulatory expert guidance |
| To what extent can consistent communication among GEd project partners increase social and political acceptance of non-transgenic GEd products? | Science communication | • Best practice communication protocols and structures |

**The theory of change**

Strategic leadership, with product-independent coordination and oversight of GEd projects by the REO, is needed across CGIAR for consistent risk management, improved development of complementary social (including regulatory) innovations and to make efficient use of in-house expertise to build network-wide capacity in GEd technologies. In the absence of such a multi-disciplinary approach to GEd scaling, the speed advantage of GEd may be lost, and the step-changes achieved from the development of multi-trait genetic improvements may be hindered, delayed or remain unrealized. Now is an opportune time to establish a platform for improved management of the GEd portfolio as the technology is becoming more acceptable, and the time-pressure of climate change is making genetic gains increasingly urgent.

WP1 **causal processes (and assumptions)** center around the leadership role and independence of the REO in addressing the social science aspects of GEd scaling. The REO will undertake ongoing consultations, impact projections, support social engagement, communications and outreach efforts, and lead MELIA for GEdI. This will inform joint planning discussions with Market Intelligence and Accelerated Breeding to maximize the contribution of GEdI priorities to the overall GI portfolio and targeted Impact Areas. Cross-Initiative collaboration and rigorous prioritization will increase the collective efficiency and effectiveness of the GI portfolio (1, 2), in a strategic approach to scaling GEd innovations (3, 4).

The capacity of CGIAR and its partners varies (5). Successful GEd solutions require multi-disciplinary input across the product lifecycle. A capacity analysis will inform a strategic plan for long-term capacity building, including identifying areas of expertise that are available (6) and that need to be convened. This will support capacity building efforts, prepare the breeding network for the expected future increase in GEd demand (7) and increase current abilities to scale GEd innovations (8).

REO will establish a platform and framework for stewardship, risk management and stage-gating of GEd projects. WP2 will be consulted in the design of the framework and feedback gained from

implementation will identify refinements, triggering continuous improvement to the oversight provided by REO. REO's central coordination will ensure that GEd projects are underpinned by common system-wide policies, guiding principles, and position statements, ensuring acceptable performance, risk and safety standards are met by all projects (8). This will increase social and political confidence and trust in the projects (9), and acceptance of GEd innovations. Further aided by best practice communication protocols, user readiness for GEd innovations will be increased. These outcomes will create the required enabling environment for GEd scaling (10, 11, 12, 13).

**Key demand and innovation** partners for WP1 are CGIAR, NARS, ARIs, policy makers (local, regional, and global), and funders. Multi-disciplinary expertise will be critical for WP1 to take on a leadership role initially for GEdI, and later to support all GEd projects within CGIAR. **Synergies** with other Initiatives (Market Intelligence and Accelerated Breeding) will ensure complementary priorities across the GI portfolio and establish relationships for the handover of GEd breeding lines to NARS and/or Accelerated Breeding in WP3.

**Risks** include unfavorable changes to licensing trends for GEd technologies from negative impacts of ongoing patent disputes/ licensing actions and policies advanced by predominant state actors (e.g., China). Risk mitigation strategies include use of international regulatory and stewardship best practices and strategic communications/outreach efforts focused on securing social license. These efforts will be implemented with local and regional research partners, regulatory bodies, NGOs, and grassroots actors to achieve better understanding GEd technology benefits that may result in increased demand for GEd crops.

### Work Package 2

| Work Package title | **Communities of Practice (CoP) for GEd product lifecycle management** |
|---|---|
| Work Package main focus and prioritization | WP2 will convene communities of practice (CoP) covering diverse expertise needed to manage GEd products across the product lifecycle. This includes the legal and regulatory aspects of delivering GEd innovations to market. Capacity development for partners will pursue a two-directional strategy: first "horizontally," covering the multidisciplinary strategy to shepherd the GEd product from development to deployment within a target country, and second "vertically," covering specific disciplines common to all country-GEd innovation CoPs. |
| Work Package geographic scope (Global/Region/Country) | Target country specific and global: (field research in ESA: Kenya, LAC: Colombia, SA: India, SEA: Philippines, Indonesia, WCA: Nigeria) |

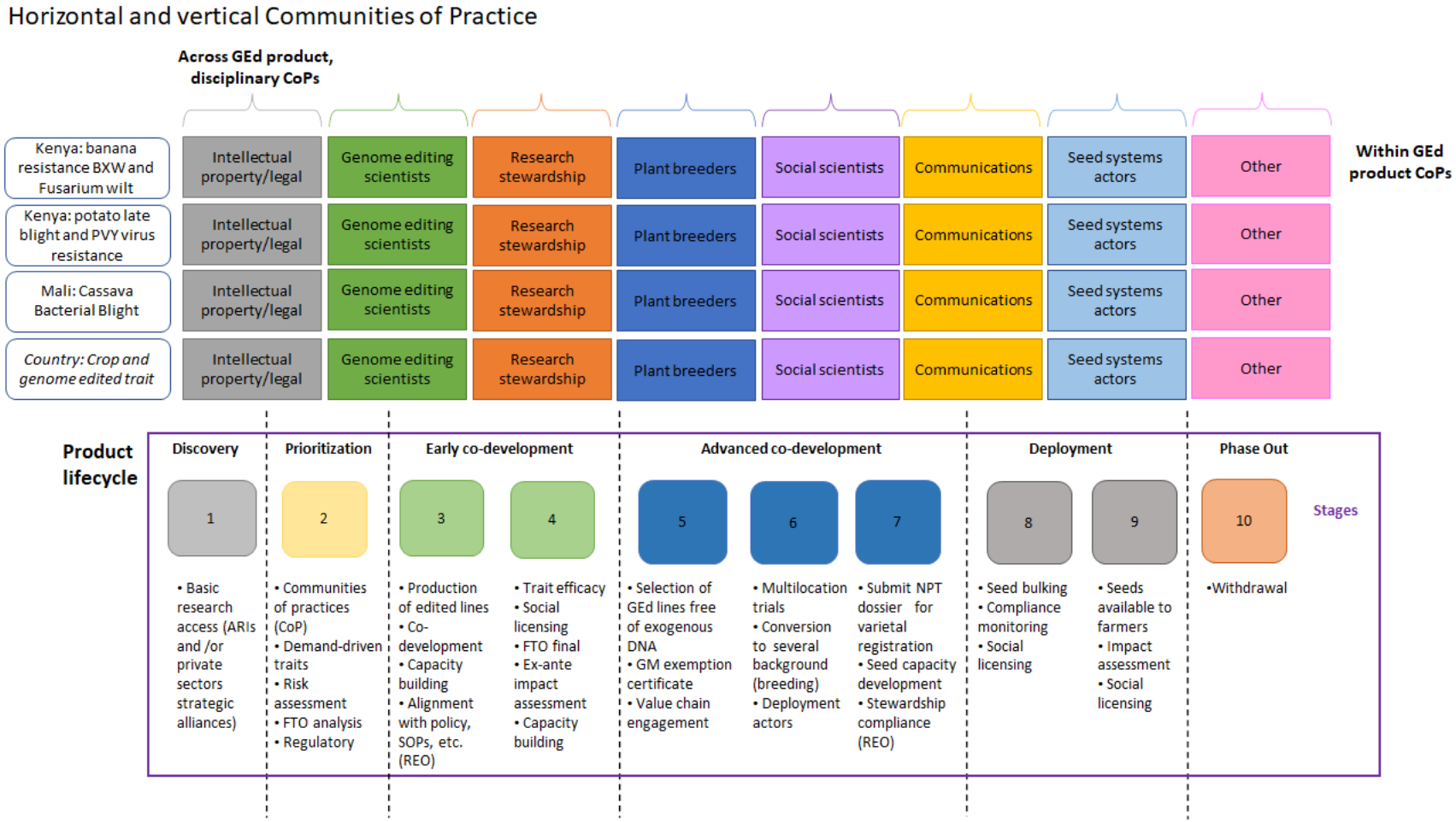



***Figure 5 Concept of horizontal and vertical Communities of Practice***

WP2 will ensure that a community of practice (CoP) is formed for each GEd product in target countries (rows). This team, with enabling guidance from WP1, will develop and implement the product lifecycle management strategy, "shepherding" the innovation from development through adoption by farmers. Disciplinary CoPs (columns) may form to exchange lessons and seek capacity development.

**The science**

CGIAR partner engagement around GEd technology must be dynamic and integrated with capacity-building efforts that are sustained across all stages of the product lifecycle. Critical actors must be involved early in the GEd product lifecycle to design a context- (country-) specific strategy to manage its lifecycle, thereby co-owning and co-implementing the strategy to achieve impact.

WP2 will support CoPs spanning the GEd product lifecycle management, including technical, legal, social, economic, communications, deployment, and other aspects. The CoPs will be guided and supported by the frameworks designed in WP1; CoPs will create a multi-disciplinary approach to capacity strengthening that includes scientific, legal, regulatory, stewardship, socio-economic analysis, and communications skills.

The CoPs will be convened with defined deliverables for members to coalesce around. This includes co-development of communication products and trait and crop specific management plans, including stewardship and risk management. These deliverables will be guided and supported by the frameworks designed in WP1. This approach will create experiential learning opportunities, embedding capacity within NARs, SMEs, and other partnering organizations to leave a legacy of in-region capacity.

One or more disciplinary CoPs may form across innovation product CoPs to share experiences and seek capacity building opportunities for their members.

| **Research Question** | **Scientific methods or activities** | **Outputs** |
|---|---|---|
| Can the formation of CoPs that co-own and co-implement GEd product lifecycle management strategies, supported with expertise assembled by WP1, achieve greater adoption of GEd crop varieties? | Initial CoP formation<br>Guidance to develop product lifecycle management strategy, including sharing of responsibilities; capacity building for sustainability | • Communities of Practice established across the product lifecycle. |
| Do communications that are developed by CoPs have greater influence on value chain and end-users? | Co-development of products, based on WP1 best practice communication protocols | • Communication products to support end-user understanding of GEd crop varieties and their products. |
| Does co-development of best practice guides and resources promote learning and capacity building within CoPs? | Training gaps filled, guided by strategic GEd capacity building plan (WP1) | • Training packages, including gender awareness training for CoPs<br>• Co-developed GEd best practice guides and supporting resources |
| Are plans that are developed by CoPs more applied to local contexts and therefore more effective? | Co-development of plans based on WP1 frameworks | • Co-developed trait and crop specific strategic plans for product lifecycle and risk management |

**The theory of change**

The core innovation in WP2 is multidisciplinary communities of practice (CoPs) that bring together expertise across the product lifecycle (4), enabling innovation scaling. CoPs are a method to build connections across the innovation ecosystem, with applied joint efforts working towards common objectives.

The **causal processes (and assumptions)** commence with REO's (WP1) support and guidance for improved GEd management across the product lifecycle. This approach will ensure the CoPs are underpinned by common standards yet are tailored to specific contexts with high levels of partner ownership during implementation. Expertise will be convened to support the CoPs' experientially focused learning as they use the frameworks provided by REO (WP1) to develop GEd best practice guides, supporting resources, and trait and crop specific strategic plans (5). Specific training packages will address gaps in knowledge, for example gender awareness and impact assessment training, resolving capacity gaps across the CoPs (3). The co-development of resources by the CoPs will share knowledge across organizations to increase the overall capacity of the CGIAR-NARs-SMEs breeding network, build knowledge to establish a solid foundation of capacity in preparation for future increased demand for GEd, and foster an enabling environment for the future release of GEd products (6).

Communication products will prepare end-users for future GEd innovations, while increased understanding of GEd will increase social acceptance, creating value chain and end-user readiness for GEd products (1), with this also supporting the enabling environment (2).

Co-developed trait and crop specific implementation plans will embed the stewardship and risk management frameworks developed by WP1 into operational contexts, and this will increase the quality of product safety outcomes (7). Demonstrated product safety will give confidence to decision-makers on the stewardship and risk management practices in place, encouraging social and political acceptance of GEd (8).

The enabling environment gained through expert supported regional capacity building with co-developed social, regulatory, and management innovations, will support the progression of GEd products to their approval for release, and post-GEdI, to market (9).

**Key demand and innovation partners** for WP2 are NARS, SMEs, government agencies, and other local partners with key roles and responsibilities for efficient product development and deployment in countries where GEd products are accepted. Working in CoPs, partners will establish GEd product lifecycle management strategies for efficient market entry, technology adoption and product dissemination, with scale considerations identified (limitations and opportunities). Social license will be sought through targeted activities at various stages during the GEd product lifecycle.

**Interdependence and synergies:** The success of WP2 relies on: 1) WP1 that will provide common best practices, regulatory and stewardship principles, and communication messages needed throughout the GEd product lifecycle; and 2) demand driven GEd products (WP3). Critical relationships with other GI Initiatives have been described above.

**Risks** to success include partners and members of CoPs who are not committed to the process of product lifecycle management; they could slow progress and undermine the process. To mitigate this risk, a sustained, consultative process will be launched to identify partners who will work collaboratively to articulate a shared vision of the Initiative and define collective roles and responsibilities.

## Work Package 3

| | |
|---|---|
| *Work Package title* | **Demand-driven GEd traits and crops** |
| *Work Package main focus and prioritization* | Our focus is first to co-develop demand-driven gene edited products focusing on climate change resilience, tolerance to biotic stresses, and nutrition. Prioritization of traits and crops adheres to the principles of demand driven, co-development with NARS, co-ownership that considers both technology opportunities and enabling environments. The activities will be conducted in partnership with NARS, ARIs, private entities and other CGIAR Initiatives. |
| *Work Package geographic scope (Global/Region/Country)* | Target country specific and global: (field research in ESA: Kenya, LAC: Colombia, SA: India, SEA: Philippines, Indonesia, WCA: Nigeria) |

### The science

WP3 will develop GEd breeding lines with demand-driven traits, as prioritized and co-developed with NARS and other partners. GEd will focus on three classes of traits: (1) pest and disease resistance; (2) climate-change mitigation and adaptation; and (3) enhanced nutrition and/or quality with a goal of focusing on one or two traits per crop. Future GEd product development opportunities will be prioritized by WP1 working with other Initiatives (mainly Accelerated Breeding and Market Intelligence) and funding sought to activate these additional projects.

GEd offers distinct advantages in speed and accuracy of breeding by eliminating the need for multiple generations of back-crossing to minimize “linkage drag” of undesirable genes that accompanies sexual crossing between elite lines and the donor parents. The technically driven advantages of GEd enable an efficient response to the increasingly pressing need for solutions to global hunger and climate change adaptation.

Review of initially selected innovations, including their replacement (should important weaknesses be identified, or partners strongly prioritize alternative opportunities) will occur in Year 2 in collaboration with Accelerated Breeding, Market Intelligence, consistent with the phase-gate criteria established with WP1.

| Research Question | Scientific method/s or activities | Outputs |
|---|---|---|
| Can we apply the knowledge of superior alleles, genes or sequences used by pathogens to identify targets and edit prioritized crop-traits with partners? | Allele mining is done through bioinformatic and phenotypic analysis in collaboration with Genebank, Accelerated Breeding and Breeding Resources. Four editing approaches, (1) gain of function by gene knock-out; (2) disrupting the sequence used by pathogens to infect plants; (3) base or prime editing to edit inferior alleles to mimic superior alleles; and (4) creating cuts in specific genome sites to harness new DNA recombination, are or will be used to develop editing tools applicable to CGIAR crops. | • Superior allele identified from non-elite germplasm source (exotic elite line, or gene bank accession) for demand-driven traits and used for editing |
| Can GEd crops with demand-driven traits significantly improve the performance and reduce the time required to develop and scale new varieties to farmers? | Direct editing is done in advanced breeding lines or farmer popular varieties followed by trait validation in confined facilities. | • GEd breeding lines with predicted step-change gains in targeted Impact Areas, including benefits for women and youth, are certified |
| Can we develop GEd innovations that are exempt from GM (transgenic) regulation in target countries? | WP3 will implement good stewardship practices for risk management and quality control of all research activities including those of other partner entities.<br>To be exempt from regulatory requirements applied to GM (transgenic) products, our GEd products will strictly implement protocols to verify that GEd product lines are free of any exogenous DNA used during the development process. Submission of evidence will follow country regulations and institutional processes.<br>A traceability methodology will be developed for quality control and in line with good stewardship practices. | • Protocols, traceability method and quality assurance processes to guarantee exogenous DNA free<br>• Applications submitted for two non-GM product regulation approvals. |

**The theory of change**

The **causal processes (and assumptions)** leading to predicted step-change gains in targeted Impact Areas commence with WP1's prioritization of identified opportunities for GEd to address many "difficult to breed" traits for climate change resilience, decreased greenhouse gas emissions, improved nutrition (including healthier cereals), more efficient nutrient use, and better tolerance to pests or diseases to reduce crop losses and increase food security.

Working with Genebanks and drawing on the allele mining studies in Accelerated Breeding and Breeding Resources, WP3 will identify superior alleles in elite germplasm and genebank accessions.

WP3 will implement co-developed trait and crop-specific implementation plans and follow best practices to develop GEd breeding lines with predicted step-change levels of improvement in the targeted Impact Areas. Validation of performance, and use of these GEd breeding lines in field trials will require prior assurance of freedom from exogenous DNA, and approval from regulatory authorities. To support this, WP3 will develop and use Excellence in Stewardship protocols, a traceability methodology developed, operating procedures to ensure exogenous DNA-free status is maintained and quality assurance processes to give certifiers confidence in the products (2). Within the three years of this Initiative, WP3 will submit at least two products for decision by regulatory authorities about their regulatory status, expecting they will not be subject to GM (transgenic) regulatory requirements (3).

By working in CoPs assembled and enabled in WP2, and on GEd products that have been identified through consultation, there will be high levels of co-ownership, user readiness for the products, and enthusiasm to include GEd lines in breeding pipelines and elite varieties (4).

The use of GEd technology to directly edit advanced breeding lines or farmer popular varieties will increase the speed that demand-driven traits can be incorporated into varieties (5). As a result, GEd products will be used to achieve step-change in the targeting Impact Areas and to incorporate the needs of women and youth in market demanded varieties (6, 7).

Our **innovation partners** will help ensure that products are thoroughly tested and ready for use supported by data and collaboration with Market Intelligence, Accelerated Breeding, Breeding Resources, and Seed Equal. Collaboration beyond the GI Action Area (RAFS, ST) will happen beyond this first phase of GEdI (after 2025). **Key demand partners** for GEd crop innovations will include farmers, consumers, and relevant NARS breeding programs. **Scaling partners:** national seed agencies and private companies will be brought on board through a collaboration with Seed Equal to eventually deliver genetic gains in farmers' fields.

WP3 envisions three potential **risks**:1) some of the product concepts are not met during the field validation process; 2) unpredictable changes in the regulatory environment which could slow product development, and 3) unanticipated contamination of exogenous DNA in the advanced GEd breeding lines. To mitigate these risks, we will employ proven GEd approaches that maximize predictable results while drawing on the expertise of CoP members to provide insight on potential regulatory bottlenecks, and apply Excellence Through Stewardship practices.

# 4. Innovation packages and scaling readiness plan

GEdI will initially invest in five GEd Innovation Packages — genome edited products (Annex 5). Innovation scaling principles have informed the design of GEd, notably the social innovations that will be needed to successfully scale the GEd products.

WP1 will drive application of innovation scaling. The REO's ongoing prioritization and GEd product lifecycle management system will require innovation readiness assessment of each potential GEd product. The product lifecycle management system and stewardship and risk management frameworks will structurally embed innovation scaling principles. The CoPs will use the lifecycle management system and implement crop and trait specific implementation plans, ensuring that innovation packaging and scaling are applied. Scaling of the GEd products is expected to occur beyond the life of GEdI. The outputs in WP1 and WP2 are designed to prepare WP3 innovations for scaling. This includes embedding innovation readiness and scaling principles in the lifecycle management system and crop and trait specific implementation plans.

The appropriate timing for a standard track innovation scaling planning is in Year 3, when the prior work of WP1 and WP2 can be used to inform readiness assessments of the social, regulatory and political landscapes, and GEd innovations may be progressing to field trial stage research. For this work, a budget of US$75,000 has been allocated in Year 3.

# 5. Impact statements

## 5.1 Nutrition, health & food security

### Challenges and prioritization

Food security in many countries is under constant threat from pests and diseases, impacting the nutrition and health status of affected populations. Currently, around 20% of farm production is lost to pests and diseases[33] [34]. Climate change induced productivity decline[35] and the growing global population will put increasing pressure on yield maximization to maintain food security.

Broad spectrum pest and disease resistance is often available only in wild species, with access to the desired traits being difficult, costly and time consuming. GEd options can offer quicker and more accurate results. The current GEd priorities will increase pest and disease resistance of staple crops, in a timely and efficient manner.

Staple crops are generally energy and carbohydrate rich, yet poor in micronutrient content, requiring diet diversification and nutrient enhancement to address chronic malnutrition, estimated to cost US$3.5 trillion per year[36]. Future priorities are likely to include biofortification solutions to alleviate micronutrient deficiency for populations that lack diversified diets.

### Research questions

- Will the current priorities need to change in response to changing global, regulatory, or other changes?
- Can we apply the knowledge of superior alleles, genes or sequences used by pathogens to identify targets and edit prioritized crop-traits with partners?
- Can GEd crops with demand-driven traits significantly improve the performance and reduce the time required to development and scale new varieties to farmers?

### Components of Work Packages

WP1 will provide a GEd lifecycle management platform that holistically brings together the technical and social (end-user understanding, regulation, governance and legal) innovations required for successful GEd projects. This platform, and associated support for capacity building, will be designed to provide underpinning support for non-GEdI GEd projects and future GEd projects. As part of the REO's oversight, ex-ante impact assessments and consultation with diverse stakeholders will identify the next set of GEd priorities, expected to include nutrition, health and food safety targets.

WP2 will take the frameworks and use the expert guidance pool created by WP1 and implement these in multidisciplinary CoPs. This will build a foundation capacity base that will be expanded as new GEd opportunities, such as biofortification, arise.

WP3 will develop the required technical protocols to manage risks and ensure product safety. These will be implemented as GEd breeding lines are progressed and deliver predicted step-change gains in the targeted Impact Areas.

### Measuring performance and results

- Predicted genetic gain of GEd breeding lines.
- Projection of benefits: Estimated increase in yield, economic and other benefits and resulting reduction in poverty and hunger, by 2030.

### Partners

The demand, innovation, and scaling partners are already identified for the priority innovations as these are legacies from existing CGIAR research projects. Partners include NARS, ARIs, SMEs, the private sector, value chain actors, farmers, consumers and other GI and non-GI Initiatives. For a detailed list see Annex 1.

### Human resources and capacity development of Initiative team

The human resources needed to implement the GEdI cover a wide range of expertise and administrative skills (see Section 9). The CoPs are a primary avenue for capacity building, as guided by the capacity audit and strategic capacity building plan developed by WP1.

## 5.2 Poverty reduction, livelihoods & jobs

### Challenges and prioritization

The GEdI product and target country selections are focused solutions to alleviate poverty, especially for the world's most vulnerable farmers who have limited access to many advanced farming interventions and practices (e.g., agrochemicals, protective equipment, certified seeds, soil nutrients)[37]. Pest and disease resistant varieties will limit the need for smallholders to make additional investments in agrochemicals if they are to attain surplus yields that can be traded, thereby increasing the profit margin of vulnerable smallholders.

GEdI will facilitate more direct technology benefits on an expanded range of crops, varieties, and traits important to smallholder farmers, addressing technological disadvantages experienced by developing countries. The GEdI addresses the research opportunities and enabling conditions needed to facilitate successful outcomes and impacts. The goal is to create poverty-reducing crop innovations that are less impacted by the range of controversies and issues surrounding transgenic crops[38].

**Research questions**

- How can NARS, SMEs and policymakers be supported to implement GEd technologies in local policy environments?
- To what extent can consistent communication among GEd project partners increase social and political acceptance of non-transgenic GEd products?
- Do communications that are developed by CoPs have greater influence on value chain and end-users?

**Components of Work Packages**

WP1 will lead high level coordination across Initiatives, including Market Intelligence and Seed Equal, to create opportunities for value chain participation (jobs, income generation, poverty alleviation) for current and future GEd product distribution. Delivery of high value GEd varieties is preferably through the private sector, especially SMEs, with spillover effects throughout the value chain, thereby meeting twin objectives of delivering higher performing crop varieties to farmers and systemic job creation.

WP2 will develop communication products to support value chain and end-user understanding of GEd, supporting future user readiness for GEd innovations and value chain job creation.

WP3 will progress exogenous DNA-free GEd breeding lines with traits and new varieties expected to increase profitability for farmers and other value chain actors, including crops with resistance to bacterial, fungal, and viral diseases to avoid up to 20% of crop losses, reducing reliance on costly agrochemicals by ~50%.

**Measuring performance and results**

- Predicted genetic gain of GEd breeding lines.
- Projection of benefits: Estimated reduction in chemical use, yield damage protection or yield increases, and resulting profit margin enhancements, by 2030.

**Partners**

The demand, innovation, and scaling partners are already identified for the priority innovations as these are legacies from existing CGIAR research projects. Partners include NARS, ARIs, SMEs, the private sector, value chain actors, farmers, consumers and other GI and non-GI Initiatives. For a detailed list see Annex 1.

**Human resources and capacity development of Initiative team**

The human resources needed to implement the GEdI cover a wide range of expertise and administrative skills (see Section 9). The CoPs are a primary avenue for capacity building, as guided by the capacity audit and strategic capacity building plan developed by WP1. WP1 will create a pool of experts, including legal, regulatory, social science and economics experts.

### 5.3 Gender equality, youth & social inclusion

**Challenges and prioritization**

Pest control is a task predominantly undertaken by women and children. In some cases, this work can be very time consuming, labor intensive (e.g., removal of BXW infected banana mats), and hazardous to health (e.g., applying pesticides without protective equipment or training). Resistant

varieties that reduce the time and labor burden will improve the livelihoods of women and create opportunities to realize childhood educational goals[39].

There is often an assumption that market driven traits will sufficiently align with the needs of women and youth. For this assumption to hold, there must be a voice for women and youth embedded in decision-making throughout the product lifecycle and value chain. Where market demanded traits do not address the differential needs and constraints faced by disadvantaged groups[40], GEd may offer the ability to quickly and efficiently insert the required traits in elite breeding lines to create complex multi-trait market demanded products that also benefit women and youth.

**Research questions**

- How can NARS, SMEs and policymakers be supported to implement GEd technologies in local policy environments?
- Does co-development of best practice guides and resources promote learning and capacity building within CoPs?
- What are the critical capacity gaps across the product lifecycle and partnering organizations?

**Components of Work Packages**

WP1 will conduct a thorough gender disaggregated projection of benefits and examination of the sociocultural and power landscape that determine benefit distribution, as informed by a systematic review of gender- and youth- based constraints and opportunities. Social mapping tools (e.g., Net-Map) will be used to identify key influence pathways for effective policy inclusion and outreach efforts to enhance benefits for women and youth. The results will be embedded into the GEd product lifecycle management system.

WP2 will implement the product lifecycle management system with defined stage-gates. The stage gates will operationalize decision-making that promotes gender equality and youth and social inclusion. WP2 will co-develop trait and crop specific implementation plans, for the prioritized traits and crops (WP1) and in accordance with the frameworks and guidance provided by WP1.

Training packages, including gender awareness training, will be completed by the CoPs (including research leaders involved in WP3). This will gain skills in methods to consider and address differential gender and youth concerns, constraints and priorities. The Gender Platform and GREAT will be approached for support to build gender responsive skills across all management and work teams.

**Measuring performance and results**

- Potential for gender and youth benefits (as determined in the systematic review).
- Projection of benefits: Gender disaggregated estimations in support of livelihood improvements of women and youth.
- Participation in gender awareness training, across the CoPs and GEd product lifecycle.

**Partners**

The demand, innovation, and scaling partners are already identified for the priority innovations as these are legacies from existing CGIAR research projects. Partners include NARS, ARIs, SMEs, the private sector, value chain actors, farmers, consumers and other GI and non-GI Initiatives. In

addition, the partners specifically to this Impact Area includes CGIAR Gender Platform, CGIAR HER+ and AWARD, GREAT, Women in Science (Kenya), ISAAA. For details see Annex 1.

**Human resources and capacity development of the Initiative team**

The human resources needed to implement the GEdI cover a wide range of expertise and administrative skills (see Section 9). The CoPs are a primary avenue for capacity building, as guided by the capacity audit and strategic capacity building plan developed by WP1. WP1 will create a pool of experts, including legal, regulatory, social science and economics experts.

### 5.4 Climate adaptation and mitigation

**Challenges and prioritization**

Climate change is creating erratic rainfall patterns, with periods of flooding and drought, altering planting season lengths and increasing unpredictable infestations of pest and disease. Climate change also lowers yields and the nutritional quality of food[41]. Solutions to climate change related production threats are urgently needed to maintain food security, reduce poverty and improve environmental outcomes.

Populations relying on clonally propagated crops (e.g., banana, cassava and potato) are particularly vulnerable, as improvement of these crops is hampered by long breeding cycles. GEd accelerated crop improvement will facilitate a more timely and efficient response from researchers, extension services, farmers, and the private sector to stabilize yields, productivity losses, and maintain nutritional quality.

Nitrogen fertilizer use is a contributor to greenhouse gas emissions (and a challenging input cost for poor smallholders). GEdI will progress nitrogen translocation in rice to improve fertilizer use efficiency, with a projected impact of 15.5 million hectares. The reduction of greenhouse gas equivalents will be estimated by WP1 as part of ongoing impact projections.

**Research Questions**

- Can a centrally managed Research Enabling and Oversight unit (REO) create enabling structures and opportunities to use GEd at scale (current and future projects)?
- Can GEd crops with demand-driven traits significantly improve the performance and reduce the time required to development and scale new varieties to farmers?

**Components of Work Packages**

WP3 will progress GEd breeding lines that improve climate adaptation and create mitigation opportunities, including climate-resilient rice with improved nitrogen use efficiency, low methane emission, and brown planthopper resistance.

**Measuring performance and results**

- Predicted genetic gain of GEd breeding lines.
- Projection of benefits: Estimated reduction in greenhouse gas equivalents (while maintaining productivity) by 2030.

**Partners**

The demand, innovation, and scaling partners are already identified for the priority innovations as these are legacies from existing CGIAR research projects. Partners include NARS, ARIs, SMEs,

the private sector, value chain actors, farmers, consumers and other GI and non-GI Initiatives. For details see Annex 1.

### Human resources and capacity development

The human resources needed to implement the GEdI cover a wide range of expertise and administrative skills (see Section 9). The CoPs are a primary avenue for capacity building, as guided by the capacity audit and strategic capacity building plan developed by WP1. WP1 will create a pool of experts, including legal, regulatory, social science and economics experts.

## 5.5 Environmental health and biodiversity

### Challenges and prioritization

Control of pests and diseases and fertilizer inputs can be expensive for smallholders, with precise applications difficult without mechanization. However, these inputs are necessary to maximize productivity. Increased resistance to pests and diseases, and improved fertilizer use efficiency, will give these smallholders greater choice in their crop management including IPM, the ability to minimize or better target input use and to increase profit margins. In agroecological zones with higher rainfall and runoff, there may also be benefits to waterway health.

The improved varieties will enhance production by minimizing the losses due to pests and disease, reducing pressure to convert natural areas to farmland, thereby maintaining biodiversity. The use of wild accessions in elite breeding lines will increase the genetic diversity of crops, preserving agricultural biodiversity.

### Research questions

- Will the current priorities need to change in response to changing global, regulatory or other changes?
- Can we apply the knowledge of superior alleles, genes or sequences used by pathogens to identify targets and edit prioritized crop-traits with partners?
- Can GEd crops with demand-driven traits significantly improve the performance and reduce the time required to development and scale new varieties to farmers?

### Components of Work Packages

The frameworks, procedures, best practice guides and methods developed by WP1, WP2 and WP3 will include considerations for minimizing the environmental impact of breeding operations, applying a cradle to grave ethos to environmental sustainability of the products produced. WP1 will assess the potential for environmental benefits in impact projections to inform prioritization of future GEd projects.

Risk management and product safety are major considerations across the Initiative. WP1 will develop stewardship and risk management frameworks, WP2 will co-develop trait and crop specific implementation plans that address risk and product safety across the product lifecycle and WP3 will develop and put in place a traceability method, quality assurance processes and Excellence Through Stewardship protocols to protect environmental health and biodiversity.

WP3 will develop improved GEd parental lines to be incorporated into breeding programs or directly released as GEd varieties with traits conferring positive environmental impacts, e.g., disease resistant main staple crops.

**Measuring performance and results**

- Ex-ante studies examining expected positive environmental and biodiversity impacts of GEd breeding lines and varieties.

**Partners**

The demand, innovation, and scaling partners are already identified for the priority innovations as these are legacies from existing CGIAR research projects. Partners include NARS, ARIs, SMEs, the private sector, value chain actors, farmers, consumers and other GI and non-GI Initiatives. For a detailed list see Annex 1.

**Human resources and capacity development**

The human resources needed to implement the GEdI cover a wide range of expertise and administrative skills (see Section 9). The CoPs are a primary avenue for capacity building, as guided by the capacity audit and strategic capacity building plan developed by WP1. WP1 will create a pool of experts, including legal, regulatory, social science and economics experts.

# 6. Monitoring, evaluation, learning and impact assessment (MELIA)

## 6.1 Results framework

| CGIAR Impact Areas | | | | |
|---|---|---|---|---|
| **Nutrition, health, and food security** | **Poverty reduction, livelihoods, and jobs** | **Gender equality, youth, and social inclusion** | **Climate adaptation and mitigation** | **Environmental health and biodiversity** |
| **Collective global 2030 targets** | | | | |
| End hunger for all and enable affordable healthy diets for the 3 billion people who do not currently have access to safe and nutritious food. | Reduce by at least half the proportion of men, women & children of all ages living in poverty in all its dimensions according to national definitions. | Close the gender gap in rights to economic resources, access to ownership and control over land and natural resources for over 500 million women who work in food, land, and water systems. | Equip 500 million small-scale producers to be more resilient to climate shocks, with climate adaptation solutions available through national innovation systems. | Stay within planetary and regional environmental boundaries consumptive water use in food production of less than 2500 $km^3$ per year (with a focus on most stressed basins), zero net deforestation, nitrogen application of 90 Tg per year (with a redistribution towards low-input farming system) and increased use efficiency; and phosphorus application of 10 Tg per year. |
| **Common impact indicators that your Initiative will contribute to and will be able to provide data towards** | | | | |
| #people benefiting from relevant CGIAR innovations<br>#people meeting minimum dietary energy requirements<br>#people meeting minimum micronutrient requirements | #people benefiting from relevant CGIAR innovations<br>#people assisted to exit poverty | #Women benefiting from relevant CGIAR innovations<br>#Youth benefiting from relevant CGIAR innovations | #tons CO2 equivalent emissions<br>#people benefiting from climate-adapted innovations | #Tg nitrogen application<br>#ha under improved management |
| **SDG Targets** | | | | |
| 2.1, 2.2 | 1.1, 1.2. | 2.3 | 1.5, 2.4 | 2.4 |
| **Genetic Innovation Action Area outcomes** | | | | |
| 2 - CGIAR & partners use high-quality market intelligence to guide the development of new varieties to meet the needs and expectations of a wide-range of users, with special attention to marginalized groups. | | | | |
| 3 - CGIAR & partner breeding programs use state-of-the art technologies to accelerate variety development and quality. | | | | |

| 5 - Cooperation & co-investment by CGIAR, public- and private- sector seed-system actors support coordinated & effective research and investment in the sector. | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 7 - Farmers have access to and use climate-resilient, nutritious, market-demanded crop varieties. | | | | | | | | | | | |
| **Initiative and Work package outcomes, outputs, and indicators** | | | | | | | | | | | |
| **Result type (outcome or output)** | **Result** | **Indicator** | **Unit of measurement** | **Geographic scope** | **Data source** | **Data collection method** | **Frequency of data collection** | **Baseline value (outcome only)** | **Baseline year (outcome only)** | **Target value** | **Target year** |
| End-of-Initiative outcome 1 | CGIAR, NARS, and SMEs use a strategic approach for scaling GEd innovations, including frameworks to mitigate risks and harness opportunities | Number of policies/strategies/ laws/regulations/ budgets/investments/ curricula modified in design or implementation informed by CGIAR research | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard data collection methods and analyses | Biannually | 0 | Start 2022 | 5 | 2025 |
| End-of-Initiative outcome 2 | NARS, end-users, and policymakers are supported in using GEd as an option to address agriculture development constraints and opportunities | Change in the capacity of key i) individuals, ii) organizations, and iii) networks | Level | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard data collection methods and analyses | Biannually | 0 | Start 2022 | Level 3 | 2025 |
| End-of-Initiative outcome 3 | NARS, ARIs, and SMEs co-develop and jointly use GEd lines in breeding programs to efficiently achieve step-change gains for demand driven traits | Numbers of in-country partner institutions and sex-disaggregated numbers of individuals participating in and/or leading GEd product lifecycle management activities | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Biannually | 0 | Start 2022 | 5 | 2025 |
| End-of-Initiative outcome 4 | NARS, ARIs, SMEs, and decision-makers use GEd technology to incorporate the needs of women and youth in market demanded | Number of reports, publications and events informing on needs or forecasting estimated benefits of | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | 0 | Start 2022 | 3 | 2025 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | products within agrifood systems | GEd crop innovations for women and youth | | | | | | | | | |
| WP1 output 1 | Research Enabling and Oversight Unit | Number of GEd projects using the REO | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 10 | 2025 |
| WP1 output 1 | Impact projection and consultation for prioritization | Numbers of analyses used for GEdI project prioritization and implementation processes | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 10 | 2025 |
| WP1 output 2 | MELIA, including GEd capacity monitoring | Number of evaluations, audits and analyses performed for GEdI projects | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 5 | 2025 |
| WP1 output 3 | GEd product lifecycle management system with stage gates defined | Number of GEd projects using the system | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 5 | 2025 |
| WP1 output 4 | Strategic GEd capacity building plan | Percentage of capacity gaps addressed by training events | Percentage | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 85 | 2025 |
| WP1 output 5 | Expert pool across the product lifecycle | Number of experts available to CoPs across the product lifecycle | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 10 | 2025 |
| WP1 output 6 | Stewardship and risk management frameworks | Number of GEd projects applying frameworks | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 5 | 2025 |
| WP1 output 7 | Legal and regulatory expert guidance | Number of legal and regulatory points of advice obtained | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 5 | 2025 |
| WP1 output 8 | Best practice communication protocols and structures | Numbers of identifiable communication and outreach instruments/materials | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 5 | 2025 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| WP2 output 1 | CoPs implement lifecycle management system | Numbers of communities of practice (CoP) formed, and of GEd product lifecycle management strategies developed and co-implemented by CoP members | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | From Project outcome | Annually | | Start 2022 | 5 | 2025 |
| WP2 output 2 | GEdI analyses, strategies and plans for GEdI product acceptance | Numbers of consultation events and participants, and prioritized lists of potential crop-traits for GEd investments | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 5 | 2025 |
| WP2 output 3 | Training packages, including gender awareness training for breeders | Number of people trained, long-term and short-term, disaggregated by gender | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 5 | 2025 |
| WP2 output 4 | Co-developed GEd best practice guides and supporting resources | Number of best practice guides and supporting resources | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 5 | 2025 |
| WP2 output 5 | Co-developed trait and crop specific implementation plans for product lifecycle stewardship and risk management | Number of trait and crop specific implementation plans | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 5 | 2025 |
| WP3 output 1 | Superior allele identified from gene bank accessions for demand-driven traits and used for editing | Number of alleles identified in gene bank accessions for demand-driven traits | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 5 | 2025 |
| WP3 output 2 | GEd breeding lines with predicted step-change gains in targeted Impact Areas, including benefits for women and youth | Report on product concept and strategic plan, and advancement in product development cycle | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 1 | 2025 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| WP3 output 3 | Traceability method and quality assurance processes developed to guarantee exogenous DNA free | Number of GEd projects implementing method and processes | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 5 | 2025 |
| WP3 output 4 | Applications submitted for two non-GM product regulations | Number of applications submitted | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | | Start 2022 | 2 | 2025 |
| WP3 output 5 | Excellence Through Stewardship protocols implemented for research quality control | Number of GEd projects implementing Excellence Through Stewardship protocols | Numbers | SEA, SA, WCA, ESA | Primary data collected through Initiative | Standard scientific methods | Annually | 2 | Start 2022 | 5 | 2025 |

## 6.2 MELIA plan

### MELIA plan

GEdI consists of three Work Packages described above. Activities to document progress towards the outcomes and impact will use a monitoring and evaluation plan built on collecting the relevant information, at intervals, while considering ongoing input from stakeholder consultations, stage gating of project development cycles, and review of progress by project and Work Package leaders. The MEL plan will follow the establishment and validation of a pipeline of deliverables contributing to the WP outputs that will realize the EIO outcomes. This will take place during the 1st quarter of each year and, for the product-based innovations, will follow the stage gate plan of the product lifecycle.

On a biannual basis, the innovation leaders and WP coordinators will share progress towards their annual deliverables in the form of a technical report (< 500 words) on agreed, established indicators as shown in the Results Framework. In addition to the technical report, other submitted reports will include a capacity building report, gender impact analysis, and updates to relevant local policy changes affecting implementation of the Work Packages. This biannual report will use a proscribed format not to exceed two pages all inclusive. This will be an effective management tool to assist the Initiative leaders identify potential delays, needed adjustments and preparations for the annual evaluation. Additionally, it will facilitate information sharing for partners, sister Initiatives, and stakeholders in the target countries.

Annual review by science leaders of the GEdI and WP coordinators will be conducted as part of the MEL plan to inform course correction needs, adjust deviations to TOCs due to new findings and/or policy changes, validate the proposed plan of activities for the following year, and recommend budget/investment decisions. The cycle of reporting and evaluation will be documented in a consensus format that provides an overarching view and understanding of the innovation lifespan, from project start to end. This will be available to aid the Office of Evaluation and Evidence/CAS and/or sponsors of the GEdI in their overall EIO evaluations.

### Impact assessment plan

Historically, CGIAR entities have conducted transformative innovations leading to impacts while generally acting independently. GEd technology is advancing rapidly but its impacts on agriculture are still evolving due to regulatory uncertainty in some countries and uncertainties around product acceptance. Nevertheless, in the last 12 months, the regulatory landscape is trending cautiously optimistic with many countries opting to exempt lines with no exogenous DNA from GM (transgenic) oversight regimes. This is especially true for some proposed GEdI target partner countries, such as Kenya, Nigeria, India, and Philippines.

With this context, impact assessments will primarily focus on: (1) *ex-ante* cost-benefit analyses to forecast the value of GEd editing to accelerate breeding platforms and realize genetic gains for famers while examining the potential, future outcomes of deployed, gender-intentional crop varieties across the five CGIAR Impact Areas; (2) documenting results, studies and policy changes facilitated by the GEdI and their contributions towards the outcomes and impacts; (3) baseline and end-of-Initiative assessment of social license. MELIA studies, identified in 6.3, are an important component of the Impact Assessment plan; they will rely on expertise and contributions from several sister Initiatives. These studies will help reorient the investment and design of impact pathways.

### 6.3 Planned MELIA studies and activities

| Type of MELIA study or activity | Result or indicator title that the MELIA study or activity will contribute to. | Anticipated year of completion (based on 2022-24/25 Initiative timeline) | Co-delivery of planned MELIA study with other Initiatives | How the MELIA study or activity will inform management decisions and contribute to internal learning |
|---|---|---|---|---|
| Ex-ante foresight study | Development of gene editing lines with focus on farmers' needs and drivers of impact | 2023 | Market Intelligence | Adjusting investment towards the most promising innovations in terms of delivery timeline and anticipated impacts. |
| Advancement in product development cycle | Report on product concept and strategic plan and advancement in product development cycle | 2025 | Accelerated Breeding, Market Intelligence | Will inform WP1 on product development phases |
| Scaling Readiness Assessment study | Two Innovation Packages out of the 5 that have received non-regulated status will be assessed for Scaling Readiness in the next phase of the GEdI | 2025 | Accelerated Breeding | Will inform the GI Initiative teams on the stewardship principles to follow when including gene-edited lines into CGIAR and NARS breeding programs. |

# 7. Management plan and risk assessment

## 7.1 Management plan

A Leadership and Management Team (LMT) will guide the development, implementation and monitoring of annual work plans to achieve the Initiative's milestones, outputs, and outcomes. Terms of reference will define the roles and responsibilities of the LMT. The LMT will initially be composed of (i) Initiative Lead and Deputy Lead, (ii) WP Leaders (3), (iii) NARS representatives from target countries (2), (iv) Project Manager, and (v) Communications Coordinator.

The LMT's roles and responsibilities will include:

1) Develop and approve the Initiative charter.
2) Lead Initiative-level interactions with other Initiatives, ensuring synergies and coordination towards achieving the GI-wide TOC.
3) Ensure appropriate staffing is available to implement the Initiative.
4) Engage external expertise as appropriate to complement or serve needs unmet by in-house expertise.
5) Prepare annual plan of work and budget and Annual Report.
6) Annually allocate budget to WPs and sub-awardees.
7) Ensure uniform administrative implementation (e.g., standard contract) of sub-awards.
8) Ensure inclusive, effective leadership of each WP.
9) Ensure development and implementation of a capacity development strategy.
10) Ensure development and implementation of a communications strategy.
11) Ensure development and implementation of a monitoring, evaluation and learning strategy.
12) Monitor implementation of best practices for risk management, research stewardship, partnership management, etc.
13) Develop a plan, organize, and lead Initiative-wide meetings.
14) Develop and implement a strategy for fundraising.

The annual budget required for project management will grow as GEdI's budget grows. Initially, budget is needed to fund 25% time of the lead and deputy lead, 100% of a Project Manager, 100% of a GEdI specific communications manager, and modest operating budgets to implement the activities of these positions.

## 7.2 Summary management plan Gantt table

| **Initiative Start: July 1, 2022** | **Timelines** | | | | | | | | | | | | **Description of key deliverables** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **2022** | | **2023** | | | | **2024** | | | | **2025** | | |
| **Work Packages** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | |
| Work package 1 | | 1 | | 2, 3 | | | | | | | | | 1. Key disciplinary expertise 75% assembled<br>2. Key disciplinary expertise 100% assembled<br>3. Audits of initial Innovation Packages completed |
| Work package 2 | | | 4 | | 5 | 6 | | | | | | | 4. CoPs established for all five Innovation Packages<br>5. Lifecycle management strategies adopted by all five Innovation Packages<br>6. At least 3 Innovation Package investments prioritized |
| Work package 3 | 7 | | | | 8 | | | | 9 | | | | 7. Genome editing research activities ongoing for all 5 initial Innovation Packages<br>8. All 5 Innovation Package research projects compliant with REO framework and criteria<br>9. All 5 Innovation Package research projects advance at least 1 stage in lifecycle |
| MELIA | | | 10 | | | 11 | | | | | | | 10. MELIA plan completed and approved by leadership team<br>11. First annual MELIA review completed, and informs Year 3 work plan |
| Project Management | | | 12 | | 13 | | 14 | | | | | | 12. Leadership and management team initial capacity development completed.<br>13. Project charter and risk management strategy completed and approved<br>14. Capacity development strategy completed and approved |
| Innovation Packages and Scaling Readiness | | | | | 15 | | | | | | | 16 | 15. Documented scaling ambition, vision of success and roadmap for use of Scaling Readiness for selected priority core innovations<br>16. Evidence-based Scaling Readiness assessment reports and related scaling strategies for Innovation Packages |

### 7.3 Risk assessment

Use of GEd technologies for crop improvement may pose unique risks which must be managed with forethought and effective mitigation plans to ensure that intended outcomes reach the expected beneficiaries. Risk management must address risks and perceived risks. These include risks those associated with scientific discovery (intended and unintended consequences of resultant products on health and the environment), regulatory and other policy requirements, market disruptions, social and ethical concerns, legal liabilities and IP, and further exacerbation of technology gaps and access in our target geographies. In fact, WP1 and WP2 are focused on early identification and planned mitigation of risks associated with use of GEd. Our risk assessment highlights areas of greatest concern and identifies interventions for risk management. It also provides visibility to key stakeholders and oversight bodies needed for effective governance in line with the Risk Management Framework of the CGIAR. Following the Initiative's approval, risk assessment measures, aided by analytics and evidence, will be integrated across GEdI's implementation plans to facilitate continuous monitoring and management.

Main risks identified are set out as follows:

| **Top 5 risks to achieving impact** (note relevant Work Package numbers in brackets) | **Description of risk** | **Likelihood**<br>Rate from 1-5<br>(1 = low) | **Impact**<br>Rate from 1-5<br>(1 = low) | **Risk score**<br>Likelihood x Impact | **Mitigations** |
|---|---|---|---|---|---|
| Discordant regulatory landscape coerces GEd products under GM regulation (1, 2, 3) | Restrictive changes to the regulatory status of non-transgenic GEd products in target countries, and any countries where surplus production is exported to. | 2 | 3 | 6 | Multiple priorities (risk would need to occur for all five priorities). There is an ability to shift priorities will allow responsiveness to limit risk occurring widely.<br>Assess the regulatory status of demand partners and prioritize projects that are most likely to meet regulatory requirements (e.g. non-transgenic, in-country staple crops).<br>Maintain collaborative relationships with project teams, local regulators, local scientists, the private sector, and other regulatory policy influencers to facilitate regulatory approvals and oversight frameworks that are science based. |
| Product Acceptance – Market and Social License – holds up GEd product release<br>(1, 2) | A combination of market (trade, market size, labeling) and social/public acceptance factors (ethics, lack of awareness, organized anti-technology campaigns) could impact final famers and consumer adoption of new GEd varieties. | 2 | 3 | 6 | As above, proactive communication, working with project teams and diverse stakeholders (govt. and value chain actors, civil society, media, communicators will be formulated initially; both internal and external skills will be tapped, including development of strategic partnerships with other GEd projects.<br>This risk is a future risk to the progression of products to commercialization. Work will commence within GEdI to mitigate this risk, but if the risk occurs, the within-Initiative objective of two certified products progressing to field trial and capacity building in preparation for increasing GEd demand will still be met. |

| | | | | | |
|---|---|---|---|---|---|
| Intellectual property landscape prevents timely and equitable delivery of products (1,2) | The primary genome editing research tool, CRISPR-Cas technology is controlled by multiple providers. It may be difficult to obtain clear FTO for commercial planting of products developed with this technology. Complicated IP arrangements may also impact agreements with the local seed companies on affordable pricing. | 1 | 3 | 3 | Discussions have already commenced with Corteva for extending CGIAR's research license use of CRISPR-Cas technology to ensure FTO for commercial release of developed products. Work has commenced and will continue in GEdI to mitigate this future risk.<br>Within the three years of GEdI, progression to field stage research trials will still be permissible under current technology licensing. |
| Some of the product concept targets are not met during the field validation process | Despite successful lab and greenhouse assays, the GEd lines do not perform as well as anticipated in the field trials. | 2 | 3 | 6 | Alternate strategies for each trait have been prepared to replace the current strategy if necessary. A phase-gate decision with external inputs to ensure that only the best GEd breeding lines are moved to the non-GM regulatory phase and the field trials. |
| Unanticipated contamination of undesirable material in the advanced GEd breeding lines. | Cross contamination between transgenic and exogenous DNA free GEd lines due to poor quality control within the same research infrastructure | 1 | 4 | 4 | Application of a strict stewardship practices to separate physical handling and growth of the GEd breeding lines with non-GM regulatory status and the other GEd materials to ensure that during multiplication and propagation of the plant material no mixing is possible. |

# 8. Policy compliance, and oversight

## 8.1 Research governance

"Researchers involved in the implementation of this Initiative will comply with the procedures and policies determined by the System Board to be applicable to the delivery of research undertaken in furtherance of CGIAR's 2030 Research and Innovation Strategy, thereby ensuring that all research meets applicable legal, regulatory and institutional requirements; appropriate ethical and scientific standards; and standards of quality, safety, privacy, risk management and financial management. This includes CGIAR's CGIAR Research Ethics Code and to the values, norms and behaviors in CGIAR's Ethics Framework and in the Framework for Gender, Diversity and Inclusion in CGIAR's workplaces."

## 8.2 Open and FAIR data assets

"The GEdI will align with the OFDA Policy's Open and FAIR requirements, ensuring:

- Rich metadata conforming to the CGIAR Core Schema to maximize Findability, including geolocation information where relevant.
- Accessibility by utilizing unrestrictive, standard licenses (e.g. Creative Commons for non-software assets; General Public License or Massachusetts Institute of Technology for software), and depositing assets in open repositories.
- Wider access through deposition in open repositories of translations and requiring minimal data download to assist with limited internet connectivity.
- Interoperability by annotating dataset variables with ontologies where possible (controlled vocabularies where not possible).
- Adherence to Research Ethics Code (Section 4) relating to responsible data (through human subject consent, avoiding personally identifiable information in data assets and other data-related risks to communities).

# 9. Human resources

## 9.1 Initiative team

| Category | Area of expertise | Short description of key accountabilities |
|---|---|---|
| Research Support (Leadership & Administration) | Biotechnology product lifecycle management; project leadership | Staff planning and oversight; leadership and oversight of research and partnership implementation. |
| Research Support (Leadership – Research) | Research Leadership and Management | Scientific quality assurance; develop and implement stage gate product advancement process; quality assurance of technical reports, establish internal and external collaborations with partner/s. |
| Research Support (Leadership – Research) | Impact assessment coordinator/facilitator | Facilitate/develop the ex-ante assessment and prioritization studies examining GEd impacts including on poverty and livelihoods, employment, biodiversity, climate change and other economic benefits, ex-ante foresight study as part of the MELIA process in coordination with Market Intelligence, facilitate coordination with MIPPI and other impact assessment teams. |
| Research Support (Leadership & Administration) | Project management | Budget management; sub-award management; donor report coordination; meeting coordination; and assist GEdI specific administration (logistics, personnel, etc.). |

| | | |
|---|---|---|
| Research Support (Leadership & Administration) | MELIA Coordinator (including consultants) | Provide oversight for all monitoring, evaluation and learning activities across the Initiative. Hiring of an external consultant anticipated to assist in setting up metrics, indicators and tracking mechanisms. |
| Research Support (Enabling Disciplines) | Legal and intellectual property management | Implement intellectual property audits for each project; liaise with One CGIAR legal and IP units for licensing negotiation and agreements to ensure freedom to operate with products; capacity development in area of expertise. |
| Research Support (Enabling Disciplines) | Regulatory and research stewardship compliance | Develop guidelines for ensuring compliance with regulatory requirements and stewardship best practices; conduct project audits; risk analysis and amelioration |
| Research Support (Enabling Disciplines) | Capacity development | Develop and coordinate implementation of a capacity development strategy for individuals, institutions, and teams; develop and implement curricula for capacity development events. |
| Research Support (Enabling Disciplines) | Community of practice (CoP) enabler | Assist project scientists to convene, inspire and build team spirit among CoPs |
| Research Support (Enabling Disciplines) | Social scientist | Design and support social consultations and social license efforts; capacity development in area of expertise. |
| Research Support (Enabling Disciplines) | Gender specialist | Review incorporation of gender in the prioritization, frameworks and crop and traits specific implementation plans. |
| Research Support (Enabling Disciplines) | Communications | Develop and implement a communications strategy to ensure excellent internal and external communications, including GEd contribution to GI AA web pages; develop communication materials; capacity development in area of expertise. |
| Research | Bioinformatics | Implement in-silico characterization of gene/s in target crops to identify target traits. |
| Research | Molecular Biology | Design guide RNAs and vectors for genome editing; molecular analysis of genome edited lines with target modification. |
| Research | Transformation specialist | Ensure effective pipeline for reagent transfer to plants |
| Research | Trait Validation | Conduct trait validation through phenotyping/assessment of genome edited lines. |
| Research | Technical specialists and experts | Targeted specialist expertise in areas such as biosafety glasshouse management; high throughput phenotyping; pathology, biochemistry, crop modelling etc. |
| Research | Laboratory technicians | Specialized and unspecialized technical and support staff; accountable for successful day-to-day laboratory activities; compliance with record-keeping and pertinent stewardship protocols. |

### 9.2 Gender, diversity and inclusion in the workplace

The gender balance of the GEdI team is currently 50/50 between male and female science leaders. However, given the uncertainty around final product selection and how that may impact participating partners, that ratio may change. Anticipating that it may not reach the minimum of 40% female professionals, we will consciously consider diversity when recruiting in line with CGIAR recruitment policies to ensure gender balance and the inclusion of minorities and under-

represented groups in key roles across the GEdI management, administrative and WP teams. This equitable access to roles and responsibilities in the GEdI will be monitored annually by the Initiative LMT.

### 9.3 Capacity development

Capacity development will be a major objective within and across the three WPs.

Activities to be conducted in first 3-6 months will include:

1. Initiative Leadership and Management Team (see Section 7.1) will complete training on: i) respectful, inclusive leadership and partnerships; ii) types of capacity development and their strategic value (continuous improvement, individual professional development, institution building; and iii) monitoring, evaluation and learning for successful project management and leadership.
2. On-line training will be extended to the entire Initiative team on: i) gender, diversity, and inclusion; ii) discrimination, harassment and how to report concerns; iii) code of conduct.
3. A Capacity Development Coordinator will be appointed and tasked with drafting a capacity development strategy for review and approval by the LMT.

Each WP will implement capacity development activities prioritized with partners and coordinated by the Capacity Development Coordinator.

WP1 will develop best-practice guidelines, project-critical checklists, and training materials (briefs, short videos, workshops) about: i) developing and implementing a holistic strategy for product lifecycle management; ii) building institutional capacities to implement GEd projects; and iii) specific skills needed to implement a holistic strategy (management of IP, stewardship, engagement with value chain actors, regulatory compliance, and risk management. While WP1 may convene some of these capacity development activities, others will be co-designed and implemented with and address needs identified by CoPs of WP2. WP1 will also suggest capacity building opportunities for WP2 partner institutions for effective co-development of genome editing projects.

WP2 will work with WP1 to prioritize, co-design and implement CoP-specific capacity development activities. For example, if social license or crisis communications pose a risk to a specific project CoP, they would seek expertise from WP1.

WP3's capacity development efforts will focus on the science and application of genome editing. Research laboratories will host visiting scientists and project partners to learn and/or participate in research projects, sometimes establishing longer-term mentorship relationships. Links with ARIs will expose GEdI scientists to novel techniques and opportunities for research collaborations and/or to enhance efficiency or effectiveness of WP3 and its partners' research.

# 10. Financial resources

## 10.1 Budget

### 10.1.1 Activity breakdown

| USD | 2022/2023 | 2023/2024 | 2024/2025 | Total |
|---|---|---|---|---|
| **Crosscutting across Work Packages**[1] | $234,607 | $504,000 | $521,500 | $1,260,107 |
| **Work Package 1** | $793,378 | $1,674,000 | $2,557,500 | $5,024,878 |
| **Work Package 2** | $532,053 | $1,674,000 | $4,445,000 | $6,651,053 |
| **Work Package 3** | $1,791,489 | $3,348,000 | $7,301,000 | $12,440,489 |
| **Innovation Packages & scaling readiness**[2] | | | $75,000 | $75,000 |
| **Total** | $3,351,527 | $7,200,000 | $14,900,000 | $25,451,527 |

[1] GEdI management costs (7%)

[2] Included in WP1 and WP2

### 10.1.2 Geography breakdown

| USD | 2022/2023 | 2023/2024 | 2024/2025 | Total |
|---|---|---|---|---|
| **Global (not specific country)** | $827,971 | $1,778,710 | $3,680,941 | $6,287,621 |
| **Region LAC** | $252,356 | $542,129 | $1,121,906 | $1,916,390 |
| **Region WCA** | $252,356 | $542,129 | $1,121,906 | $1,916,390 |
| **Region ESA** | $1,261,778 | $2,710,645 | $5,609,530 | $9,581,952 |
| **Region SA** | $252,356 | $542,129 | $1,121,906 | $1,916,390 |
| **Region SEA** | $504,711 | $1,084,258 | $2,243,812 | $3,832,781 |
| **Total** | $3,351,527 | $7,200,000 | $14,900,000 | $25,451,527 |

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