Distribution Agreement

In presenting this thesis or dissertation as a partial fulfillment of the requirements for an advanced degree from Emory University, I hereby gran to Emory University and its agents the non-exclusive license to archive, make accessible, and display my thesis or dissertation in whole or in part in all forms of media, now or hereafter known, including display on the world wide web. I understand that I may select some access restrictions as part of the online submission of this thesis or dissertation. I retain all ownership rights to the copyright of the thesis or dissertation. I also retain the right to use in future works (such as articles or books) all or part of this thesis or dissertation.

Signature:		
Bethany Larkin	Date	_

Approval Sheet

Advancing Healthcare Innovation in Africa: A case study and recommendations for AHIA, a program of Emory University

By

Bethany Larkin Master of Public Health

Hubert Department of Global Health

Deborah McFarland, PhD, MPH Committee Chair

Advancing Healthcare Innovation in Africa:

A case study and recommendations for AHIA, a program of Emory University

Bethany Joy Larkin B.S., Rhodes College, 2013 M.B.A, Emory University, 2020

Emory University

2021

Thesis Committee Chair: McFarland, Deborah PhD.

A thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master of Public Health in Global Health.

2021

Abstract

Advancing Healthcare Innovation in Africa: A case study and recommendations for AHIA, a program of Emory University

By Bethany Larkin

Health biotechnology innovation not only supports economic development and job creation, it also addresses key needs in the rapidly changing global health landscape. In order to thrive, biotechnology innovation needs an enabling ecosystem to support it that includes regulatory considerations, mentorship, networks, intellectual property, and funding. Currently, Africa lags behind other regions of the world in supporting health biotechnology despite a high disease burden that necessitates innovative solutions. AHIA, Advancing Healthcare Innovation in Africa, is a multi-disciplinary program of Emory University that aims to address and solve unmet health needs in Africa by supporting and promoting the advancement of health innovation and technologies. The purpose of this special studies project is to document a history of the AHIA, provide a case study of the program from 2017-2019, and provide key recommendations for the program moving forward in the context of the health biotechnology ecosystem in Africa. AHIA supported 21 innovators in medical devices, diagnostics, health technologies, and pharmaceuticals between 2017-2019 and 46 students from Emory University. Innovators found aspects of the AHIA program, such as networking and intellectual property strategy, useful to advancing their innovations. They noted key opportunities for improvement to the program including adding cultural-awareness training for traveling students, creating innovator support continuity, improving program design and communication, and reviewing the program location. Recommendations are provided based on this feedback for how AHIA can best position itself as a program moving forward. Health biotechnology ecosystems have the potential to not only address global health problems, but also build robust local economies around the world. Global programs from high-income countries, like AHIA, can play a key role in supporting healthcare innovators in Africa through connections to resources and supporting initiatives led by African organizations to create a sustained ecosystem.

Advancing Healthcare Innovation in Africa:

A case study and recommendations for AHIA, a program of Emory University

By

Bethany Larkin

B.S., Rhodes College, 2013 M.B.A, Emory University, 2020

Emory University

2021

Thesis Committee Chair: Deborah McFarland, Ph.D.

A thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master in Public Health in Global Health.

Acknowledgements

My gratitude to the AHIA program at Emory University. Attending the AHIA workshop in 2019 sparked in me a deep curiosity for innovation, entrepreneurship, and examining how practitioners can think about global health through a multi-disciplinary lens. Specifically, I thank Dr. Dennis Liotta who encouraged and supported me in stepping into a student-leadership role for the AHIA program in 2020.

Thank you to the AHIA Leadership team for your time sharing your experiences with the AHIA program and providing the documentation needed for this report.

To the innovators who participated in interviews, thank you not only for your honest feedback and perspectives on the program, but also on the growing landscape of healthcare innovation in Africa that you participate in daily. I was truly inspired by the grit and determination you bring to addressing unmet medical needs.

Thank you to the many faculty and staff at Emory University who provided perspectives on innovation, healthcare, and entrepreneurship.

Finally, my deepest gratitude to Deborah McFarland. As a dual-degree student, standing between the two paradigms of public health and business during my time at Emory was uncomfortable and, at times, contradictory. You were always there to support me in learning how to navigate a multi-disciplinary landscape through sharing experiences, brainstorming disruption, and most importantly, helping me re-focus on priorities. I have benefited more than I could imagine from the support and time you have poured into me the past two years. Thank you!

Table of Contents

ACKNOWLEDGEMENTS	6
CHAPTER 1: INTRODUCTION	1
Rationale	1
PROBLEM STATEMENT	2
PROJECT PURPOSE	2
SIGNIFICANCE STATEMENT	3
CHAPTER 2: LITERATURE REVIEW	3
I. Innovation	4
Defining innovation	
Innovation as a tool to support Sustainable Development Goals	
Innovation in global health	
Creating an enabling environment and partnerships	8
II. BIOMEDICAL INNOVATION IN AFRICA	14
Africa disease burden	
Innovation metrics in Africa	
Investment	
Knowledge	
Intellectual Property	
Entrepreneurial ecosystems	
Opportunities for health biotechnology in Africa	
III. Conclusion	21
CHAPTER 3: METHODS	22
I. RESEARCH DESIGN	22
II. COLLECTION OF DATA AND INFORMATION	
III. Analysis	
IV. ETHICAL CONSIDERATIONS	
V. STRENGTHS AND LIMITATIONS	27
CHAPTER 4: RESULTS	28
HISTORY OF AHIA PROGRAM	
INNOVATOR STORY	
ADVANCING HEALTHCARE INNOVATION IN AFRICA	
EVOLUTION OF THE AHIA PROGRAM	
AHIA & ANDi: 2015-2017	
AHIA Present Day (2017-2019)	
AIMS AND GOALS	
Innovator Profile	
Healthcare and Economic Promise	
Student Profile	
KEY TAKEAWAYS FROM THE AHIA WORKSHOP	
Program Strengths	
Opportunities for growth	
Innovator Needs	
RECOMMENDATIONSCOVID-19 OPPORTUNITY	
CHAPTER 5: DISCUSSION AND CONCLUSION	62

REFERENCES	65
APPENDIX	68
APPENDIX 1: AHIA INNOVATOR INTERVIEW GUIDE	68
APPENDIX 2: INNOVATOR SPOTLIGHTS	70
APPENDIX 3: AHIA PROGRAM EVOLUTION FROM 2007 (APPROX.) TO PRESENT	74
APPENDIX 4: AHIA WORKSHOP RECOMMENDATIONS	75

Chapter 1: Introduction
Rationale

The global health industry is undergoing a radical transformation (Salihu and Azuine 2020). Patient demographics, disease outbreaks, exponential growth of health technology are all influencing the global health landscape as never before and placing public health issues on center-stage requiring global health professionals to think differently about solving global health issues (Salihu and Azuine 2020). This rapid change is reflected also in the global healthcare industry spending over \$100 billion annually on novel innovation and research (Dutta et al, 2019).

African countries comprise 69% of the bottom 20% of world economies (CIA 2021) and have high levels of disease burden (WHO 2020). On a regional average, Africa bears the burden of the highest maternal mortality ratios, HIV infections, incidences of tuberculosis, malaria incidence, and the second highest probability of dying of a non-communicable disease. Entrepreneurship and innovation programs are prolific across Africa. Over 600 accelerators and innovation hubs exist across the continent (Sibanda 2021). There is a growing sentimentality that 'we need African-led solutions and those solutions must by created by Africans' (Sibanda 2021). Despite the proliferation of support organizations, startups still face a number of ecosystem challenges including un-customized government programs, lack of incubators, inadequate professional services and unreliable assets including finance, leadership development, and overall infrastructure (Kansheba 2020). Additionally, many of these programs focus on social entrepreneurs or micro-businesses and cannot support the unique challenges faced by health

biotechnology (heavy initial capital investment, long time lines, regulatory constraints, intellectual property strategy) (Sibanda 2021).

Emory University, based in Atlanta, Georgia, USA, is a globally recognized research and academic institute with a specific focus on healthcare and health sciences. In the mid-2000s, AHIA, Advancing Healthcare Innovation in Africa, formed from a group of multi-disciplinary staff and faculty at the university. While AHIA has had a number of iterations, its aim has remained to leverage Emory's expertise in business, law, and biomedical commercialization to partner with industry leaders in the growing biomedical industry in Africa (AHIA 2021). Being founded by business and science faculty, the program operates much like an early-stage start-up and has not been guided by a global health methodology that incorporated key principles for program design, implementation, or monitoring and evaluation.

Problem Statement

To date, AHIA program has not been evaluated to understand the program's role in supporting early-stage innovation in Africa's biomedical industry or its success as capacity building program.

Project Purpose

The purpose of this special studies project is to document a history of the AHIA program at Emory University and provide context to the biotechnology innovation landscape in Africa. Using a case study approach, this project addresses the following:

• Documents the evolution at Emory of supporting biotechnology innovation in Africa

- Develops a profile of innovators and students who have participated in AHIA over the past three years
- Consolidates feedback on the AHIA workshop from innovators' perspectives
- Provides key recommendations for the continuation and operationalization of AHIA

Significance Statement

While AHIA supports early-stage start-ups, as a program, AHIA is in a start-up phase of its own. By documenting the successes and opportunities for the AHIA workshop and contextualizing the program in the larger biotechnology innovation landscape in Africa, key recommendations will be developed to provide a basis for designing the future of the AHIA program.

Chapter 2: Literature Review

As a program, AHIA hits on a number of key topics that cross multiple disciplines and topics including: business, law, entrepreneurship, R&D, social impact, cultural exchange, education, investment, biomedical innovation, mentorship, economic development, product commercialization, and global health. While the design of this paper is to provide a context and review of the AHIA program, these topics are too expansive for one paper. For the purpose of this literature review, the key words used were innovation, health biotechnology, entrepreneurship, intellectual property, and investment in the context of Africa. Research focused on a pan-African level for two reasons. First, AHIA has operated as a pan-African organization with innovators coming from 10 countries for the three years encompassed in this study. Second, AHIA's 2015-2017 partner, ANDi, and current partner, AfricaBio, are both pan-African organizations that focus on developing biotechnology innovation on a regional scale. One reason

for a regional focus for biotechnology is to pool and consolidate limited resources between countries. Organizations such as SanBio, to support collaborative research and development, and ARIPO, to support intellectual property protections, are developed with this same regional vision to support growth in the biomedical sector. A second reason for a regional and pan-African view is that biomedical innovation requires a significant amount of startup capital. Many African countries do not have an expansive enough national market to support commercialization and scale up of biomedical products within one country alone. Taking a 'birds-eye' view of regional and continental trends creates a better understanding of some of the levers at play impacting more local policies.

I. InnovationDefining innovation

Innovation is a general term used to describe the process of deriving value from new ideas through products, services, or business models. Innovation is elusive and complex as it is not only about the new idea itself, but also includes the implementation and adoption of a new idea in the market (Forum 2019). Innovation rarely occurs as an isolated event and often is supported in an ecosystem approach that includes key enablers like start-ups, businesses, investors, governments and academic institutions (Chataway, Chaturvedi et al. 2009, Forum 2019). Innovation has been touted as a key tool for countries becoming more competitive, adaptable, and improving quality of life (OECD 2018).

Innovation as a tool to support Sustainable Development Goals

The Sustainable Development Goals encompass 17 goals with specific targets and indicators to improve development on a local, national, and global level. The SDGs are not stand-alone goals

but interconnected along economic, social, and environment factors (Cerf 2018). While the concept of fostering innovation is included in Goal 9, "Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation", innovation, much like the SDGs themselves, is not a stand-alone concept. In the *OECD's Science, Technology and Innovation Outlook 2018*, the authors point to growing demands on innovation as no longer just a tool for job creation and economic growth, but also a tool in addressing global challenges outlined in the Sustainable Development Goals including healthcare, economic development, climate change, and clean water (OECD 2018). "In line with the SDGs, governments are seeking to redirect technological change from existing trajectories towards more economically, socially and environmentally beneficial technologies, and to spur private science and technology innovation investments along these lines" (OECD 2018). This gives rise to what the authors refer to as a new era of "mission-oriented" innovation which will require an even closer-knit ecosystem to support innovation.

Innovation in global health

The global health industry is undergoing a radical transformation (Salihu and Azuine 2020). Patient demographics, disease outbreaks, exponential growth of health technology are all influencing the global health landscape as never before and placing public health issues on center-stage requiring global health professionals to think differently about solving global health issues (Salihu and Azuine 2020). This rapid change is reflected also in the global healthcare industry spending over \$100 billion annually on novel innovation and research (this accounts for approximately 20% of global R&D spend) (Dutta et al 2019). Braithwaite et al. in *The future of health systems to 2030* write, "If global health systems are to be sustainable, they will need to adapt to the ever-evolving challenges and constant pressures wrought by rapid and

unprecedented change" (Braithwaite, Mannion et al. 2018). One of the ways to adapt to challenges is through leveraging innovation to drive change. Braithwaite et al. point to emerging technologies, genomics, new models of care, and demographic shifts as trends that will influence health systems in the future. While existing health technologies should be leveraged to address health system needs, many LMICs heavily rely on imports of innovation and technology, which is not enough to develop sustainable health care systems (Chataway, Chaturvedi et al. 2009). It is important for countries and regions to build their own innovation ecosystems to tailor innovation to their local, contextual needs (Chataway, Chaturvedi et al. 2009). As an example of this, from 1975 to 2004, 1.3% of new pharmaceuticals developed were designated for tropical diseases and tuberculosis, even though these diseases account for 12% of the global disease burden (Simpkin, Namubiru-Mwaura et al. 2019).

Lower- and middle-income countries (LMICs) bear much of the global disease burden and are uniquely positioned to contribute innovation in healthcare that is both affordable and high quality for their own context and the larger global health market. High quality and affordable healthcare are important for economic growth and a quality of life. Medical innovation is a critical tool for closing the gap of healthcare provision in support of SDGs and Universal Healthcare Coverage (Soumitra Dutta 2019). Innovations from LMICs often are developed with low-cost, low-resource environments in mind and can be leveraged to lower the cost of healthcare worldwide (examples include the use smartphones by community health workers to facilitate real-time data collection and provide patients with information) and address the needs of low-resource and remote settings across the world. Countries in Africa, Central and Eastern Asia, and Latin America are seeing medical innovation in the form of novel uses of existing technology adapted

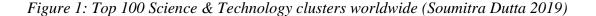
to low-resource settings (Soumitra Dutta 2019). While healthcare innovation in LMICs is rising, there is a long way to go for global adoption of medical innovation from LMICs. To date though, there are very few examples of LMIC innovations adopted by high-income countries (often referred to as reverse innovation) (Harris M 2015).

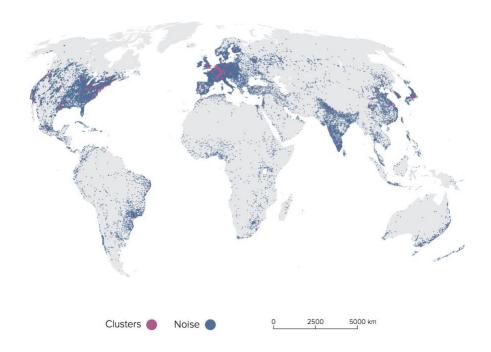
In her book, *Synthesizing Hope: Matter, Knowledge and Place in South African Drug Discovery*, Anne Polluck writes an ethnographic study of iThemba Pharmaceuticals, a small South African start-up with a mission of drug discovery for tuberculosis [TB], human-immunodeficiency virus [HIV], and malaria. As part of the study, she points out that her analysis combines the study of global health and postcolonial science, "two spheres that are not often thought about together". In these muddy waters, she explores the need for innovation in global health by African scientists for African healthcare problems. As one example for the need for local, global health innovation, Pollock reviews a common medication requirement to 'take x times daily with food'. This simple medication instruction seems simple and clear to a consumer in a high or middle-income country; however, for a patient who struggles daily with hunger and food insecurity, Pollock asks 'how should the patient manage their condition'? She argues that local innovators are more attuned to the needs of patients in their context to ensure that innovation is designed for the intended consumer appropriately (Pollock 2019).

In the world of COVID-19, the idea of global health innovation has launched rapid timelines, multi-disciplinary collaborations across the world, and new ideas to address the global pandemic. The response to the COVID-19 pandemic is evidence that achieving global health innovation to solve critical healthcare problems is possible in other areas as well (Palanica and Fossat 2020).

Creating an enabling environment and partnerships

Innovation rarely exists in isolation. Instead, it needs an ecosystem or an enabling environment to thrive. This is particularly true for health biotechnology innovation which is usually costlier, sees more failures, has more regulatory challenges, and typically has a longer commercialization timeline compared to other sectors (Sibanda 2021). Having multiple players and a collaborative environment allows for healthcare innovation to advance more quickly. Additionally, there is a need for innovation ecosystems to be built in LMICs to support scientists and innovators addressing the localized context of global health issues that might not be a research priority in a high-income country (Pollock 2019). These ecosystems tend to be geographically concentrated and clustered near strong since and technology centers (Soumitra Dutta 2019). As seen in Figure 1, these clusters of science and technology largely exist in high- and middle-income countries.





Government and industry leaders around the world are working to build innovation ecosystems to create this enabling environment for innovators to develop and grow new ideas with both 'mission-oriented' innovation and economic development in mind. Some of the levers used to drive this build include grants and tax incentives, co-investment with private business, research and development grants, education and skills training, and regulatory reform (Forum 2019). Creating these enabling environments for innovation to thrive is no simple task.

Key factors in innovation ecosystems

In 2004, Thorsteinsdottir et al. consolidated what they believed to be a first-of-its-kind comparative study on successful health biotechnology sectors in developing countries in order to define characteristics needed to build an appropriate sector. They concluded that LMICs that can successfully develop capacity in health biotechnology will see dual benefits of increased health product availability for their populations and strengthened economic development. In their analysis of seven countries' health biotechnology sectors, they discovered a number of lessons learned for what makes a successful health biotechnology sector in LMICs. These include a focus on local health needs, developing international linkages, attention to the regulatory environment, long-term government policy vision and strategy, exploitation of competitive advantages including indigenous knowledge, and meeting international standards. They also verified that close linkages among ecosystem players as well as active knowledge flows are crucial for innovation to occur (Halla Thorsteinsdóttir 2004).

Building off of their 2004 work, in 2011, Thorsteinsdóttir et al examined the role of health biotechnology innovation on a global stage specifically examining the need for global collaborations between high-income countries and LMICs. "We can no longer view the health problems of developing countries as fundamentally different from those found in high-income nations, and so addressing these problems requires a global approach. To address shared health problems requires investment in research and innovation, as well as active contributions by all affected countries." (Thorsteinsdottir, Ray et al. 2011). Specifically, they call out the need for capacity building, economic development, access to research material, and access to expertise and technologies in collaborative partnerships and exchange.

Key challenges

Thorsteinsdottir et al. also point out key challenges to creating this enabling environment in LMICs. These challenges include lack of financial resources, lack of knowledge about intellectual property rights, and diverse regulations (Thorsteinsdottir, Ray et al. 2011). Specifically examining the African region, Simpkin et al. notes key challenges to encouraging investment in health biotechnology as lack of ownership of research agendas by LMICs, poor capacity retention, institutional weakness (corruption and instability), and inadequate knowledge (Simpkin, Namubiru-Mwaura et al. 2019).

1. Lack of resources

The United States and the countries in the EU appear to have the most funding allocated to research collaborations with LMICs (Thorsteinsdottir, Ray et al. 2011). There are both financial and knowledge-sharing benefits for LMICs to partner with these high-income countries.

However, the authors warn that an imbalance can occur in these relationships and skew research

priorities to the needs of the high-income countries and the research areas that they prioritize. This imbalance has limited the ownership of research by LMICs and their role is often diminished to only that of a supplier of research material instead of a co-collaborator (Thorsteinsdottir, Ray et al. 2011).

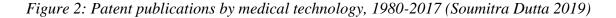
This concern is echoed in a number of places in the literature as a problem in global health research and practice. In Synthesizing Hope: Matter, Knowledge and Place in South African Drug Discovery, Anne Pullock explores how the geography of scientific knowledge matters in biotechnology innovation and post-colonial science. "African collaborators are not recognized as the true global knowledge makers. Frequently, data are extracted from the South (used to describe LMICs) and analyzed in the North (mainly high-income countries), which fuels northern science and exacerbates North/South disparities in research capacity rather than ameliorating them" (Pollock 2019). Simpkin et al. shares both the value of international partnerships that provide funding but also highlights challenges of priority misalignment, ownership and leadership of the research, and lack of sustainability (Simpkin, Namubiru-Mwaura et al. 2019). This same notion is echoed by African leaders in the entrepreneurship space. These leaders see an influx of foreign funders, which is overall positive; however, they share a hesitation that "these investors lean towards innovations that identify with their global context as opposed to local context" (Sibanda 2021). Finally, Chataway et al. notes that there is a lack of understanding between the healthcare industry and individuals who work in research, development, and innovation (which often exists disproportionately in high-income countries). "Unless researchers and producers network with local users and consumers, they are much less likely to respond to local needs (Chataway, Chaturvedi et al. 2009).

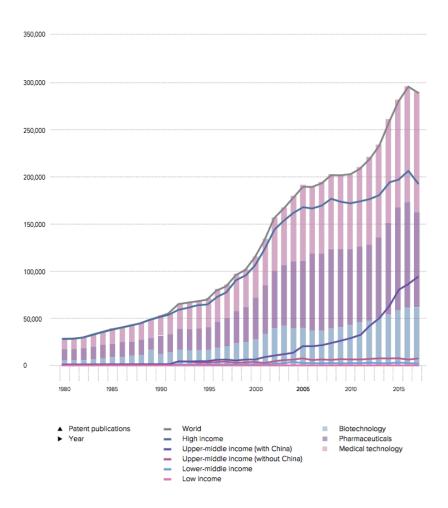
As recently as April 2021, this concern about global partnerships and funding dynamics in research and global health echoes in the literature. In an open letter, Erondu et al. challenge the international funder community to examine their role in 'decolonizing' global health. While they recognize the progress that multi-million dollar funded research and programs have had on global health, they argue that "we believe that in the same way we have to apply innovation in our work to fight diseases, innovation can be applied to the design of sustainable funding models with local researchers and organizations at their center... There is a way to create equitable and dignified partnerships and to defeat the diseases that threaten everyone" (Erondu, Aniebo et al. 2021).

2. Fragmented intellectual property knowledge

In addition to lack of resources, another challenge is a lack of intellectual property knowledge. According to World Intellectual Property Organization in 2018, there was a global 189% increase of patent applications and a 388% increase of design applications over the past 20 years reflecting the growing importance of technology and innovation in the global economy (WIPO 2019). In 1997, 88% of all patent applications were submitted from high-income countries. There is a slow shift toward more diversity in economies submitting applications. In 2017, the country of origin for patent applications was almost equally distribited between high- and upper middle-income countries (mostly driven by China) (Soumitra Dutta 2019). Despite the growth in applications for intellectual property rights and international programs, innovation still remains largerly concentrated in a handful of countries (Soumitra Dutta 2019). As seen in Figure 2, LMICs contribute little to the global intellectual property landscape in medical technologies. This dynamic is shifting. According to the World Innovation Index, many LMICs have placed

innovation on their national agendas to boost the local economy and support social development, including how to support intellecutual proptery creation for local innovation including education and regulatation.





3. Diverse regulatory environments

The final challenge in creating an enabling environment and cross-boarder collaborations for high-income countries to partner with LMICs is the variation of regulations across borders. This

can include customs requirements, manufacturing, patent protections, and more. The health biotechnology sector has become increasingly global with supply chain phases occurring across the world (Thorsteinsdottir, Ray et al. 2011). This collaboration has the potential to drive health innovation even further; however, the administrative and regulatory paperwork, customs regulations, varied classifications of products, and more can make these collaborations very challenging.

II. Biomedical Innovation in Africa

Africa disease burden

While Africa is a continent rich in diverse cultures and resources, African countries comprise 69% of the bottom 20% of world economies (CIA 2021) and have high levels of disease burden (WHO 2020). On a regional average, Africa bears the burden of the highest maternal mortality ratios, HIV infections, incidences of tuberculosis, malaria incidence, and the second highest probability of dying of a non-communicable disease (Table 2).

Table 2: Health indicators by world region (WHO 2020)

	MATERN AL MORTALI TY RATIOD (PER 100 000 LIVE BIRTHS)	NEW HIV INFECTI ONS ^G (PER 1000)	TUBERC ULOSIS INCIDEN CE ^H (PER 100 000)	MALARI A INCIDE NCE ^I (PER 1000 POPULA TION AT RISK)	PROBA BILITY OF DYING FROM ANY OF CVD, CANCE R, DIABET ES
		1.07	221	220.2	20.6
AFRICAN REGION	525	1.07	231	229.3	20.0

SOUTH-EAST ASIA REGION	152	0.09	220	4.9	23.1
EUROPEAN REGION	13	0.19	28	0.0	16.7
EASTERN MEDITERRANEAN REGION	164	0.07	115	10.0	22.0
WESTERN PACIFIC REGION	41	0.06	96	2.6	16.2
GLOBAL	211	0.24	132	57.4	18.3

Science, technology and innovation that both address localized needs and contribute to the world economy are key to Africa's growth and addressing this disease burden.

Innovation metrics in Africa

In the Global Innovation Index 2019 which examines innovation growth and trends around the world, it is clear that high-income countries far surpass R&D expenditure compared to LMICs (Soumitra Dutta 2019). While Africa ranks the lowest in terms of innovation economies by region, there are key stand out countries highlighted in the report. South Africa, Kenya, and Mauritius rank in the top innovative countries in sub-Saharan Africa. Rwanda, Tanzania, and Senegal are all seen as top innovation economies among LMICs world-wide. Since 2012, Sub-Saharan Africa has boasted more innovation achievers (defined as overperforming in innovation relative to peers) than any other region in the world (Soumitra Dutta 2019).

Specifically, the world geography of medical innovation is shifting to include many emerging economies across the world. This is seen as a result of increased demand for improved services in the growing middle class and increasing R&D, patents, and investment in these countries (Soumitra Dutta 2019). According to Africa Health Business, recent estimates indicate that the African health sector will be valued at \$259 billion by 2030 potentially creating over 16 million

jobs (Mumley March 30, 2021). This last market indicates great opportunity for innovation and support of the healthcare sector if an enabling environment can be supported.

The next section reviews the key components needed to support innovation ecosystems in Africa namely investment, knowledge, intellectual property and partnerships.

Investment

R&D pipelines to address diseases disproportionately affecting populations in Africa are insufficient despite the fact that the Africa region has 25% of the global disease burden (Simpkin, Namubiru-Mwaura et al. 2019). While 15% of the world's population lives in Africa, only 1.1% of global investment in R&D is represented on the continent (Simpkin, Namubiru-Mwaura et al. 2019). The investment that does exist is largely driven by government with a significant portion coming from international funding. The investment from the private sector is limited largely due to challenges with unstable political environments and corruption. In order for biomedical innovation to grow, collaborative and innovative financing mechanisms will be needed to foster R&D. There are differing opinions on where investment is needed. Overall, many consider the need for pan-African venture capital and investment since many foreign investors view African-led ventures as 'too risky'. The continent is a long way off from achieving this goal. Until that point, innovators must navigate an uphill battle to convince foreign investors that their innovation is worth the risk (Sibanda 2021).

That being said, some African leaders in the innovation space argue that funding is not the problem, instead, there is a challenge on where along the innovation value chain funds are needed. Specifically, in biotechnology, these leaders argue that more investment is needed in

early innovation stages of proof-of-concept for African-led innovation to get off the ground to the stage where they can attract outside investment (Sibanda 2021).

Knowledge

Countries in Africa are often not seen as key players in global health research and innovation despite having an inequitable share of global disease burden and extensive natural resources (Chataway, Chaturvedi et al. 2009), Only 2% of the world's research is attributed to Africa. Africa is estimated to have 198 researchers per million inhabitants compared to over 4000 in high income countries like the UK and the US (Simpkin, Namubiru-Mwaura et al. 2019). Many African researchers leave the continent with over 10% of sub-Saharan Africans with graduate degrees immigrating out of the continent. This causes a drain on research based in African countries. In order to sustain health research and innovation programs, strong scientific talent pipelines and high-quality universities are needed. Currently, most African researchers have a majority of their publications with international coauthors as opposed to local or regional coauthors. However, evidence shows an estimated 60% growth in publications that include African authors from 2008-2014. When looking at the pharmaceutical industry, 37 African countries have pharmaceutical production, though many do not manufacture active ingredients (Simpkin, Namubiru-Mwaura et al. 2019).

Intellectual Property

The African Regional Intellectual Property Organization (ARIPO) was established in 1976 to strengthen Africa's intellectual property system. Within the ARIPO agreement, the 19-member states agreed to pool resources to support the greater region's development in economic, science, and technology (Santos 2019). Since its founding, IP patent applications have remained low with

only 2.5% of applications originating from ARIPO-participating countries and only 8.5% from other African countries. A similar pattern was cited for industrial designs (Santos 2019). The low uptake of IP by African innovators implies that the regional collaboration to promote innovation may not be aligned yet with national policies. There is also a need for education and awareness that ARIPO can aid and support African innovators aiming to commercialize and grow their innovations. In Sibanda's recent book, Nuts and Bolts: Strengthening Africa's Innovation and Entrepreneurship Ecosystem, he emphasizes the importance of intellectual property as a tool for growth in Africa. "What is important to recognize as well is that intellectual property is the currency in the new world order of the knowledge-based economy- if you have it, you are in a better position to negotiate- if you don't have it, you could still smartly access others' intellectual property to your benefit" (Sibanda 2021).

Entrepreneurial ecosystems

Entrepreneurship and innovation programs are prolific across Africa. Over 600 accelerators and innovation hubs exist across the continent (Sibanda 2021). There is a growing sentimentality that 'we need African-led solutions and those solutions must by created by Africans" (Sibanda 2021). The Aspen Network of Development Entrepreneurs, ANDE, sponsors chapters for entrepreneurial support organizations around the world including ones in West Africa, East Africa, and South Africa. In Nigeria alone, ANDE has 99 members that include investors, capacity builders, research institutes, accelerators, and more demonstrating the vast amount of interest in supporting entrepreneurship (ANDE 2021). This innovation ecosystem is vital to support entrepreneurs, especially given that small enterprises comprise 70% of job creation and contribute about 60% of many African countries' GDP (Kansheba 2020).

Despite the proliferation of support organizations, startups still face a number of ecosystem challenges including un-customized government programs, lack of incubators, inadequate professional services and unreliable assets including finance, leadership development, and overall infrastructure (Kansheba 2020). Additionally, many of these programs focus on social entrepreneurs or micro-businesses and cannot support the unique challenges faced by health biotechnology (heavy initial capital investment, long time lines, regulatory constraints, intellectual property strategy) (Sibanda 2021).

Opportunities for health biotechnology in Africa

Healthcare innovation to address the sustainable health goals crosses into muddy waters of global health, biotechnology industry, academia, law, and regulation. It takes a multi-faceted approach to develop an enabling environment to support and drive innovation. Localized innovation that can set the research agenda and prioritize R&D activities on disease areas endemic to a region is crucial.

African-led Solutions

Currently, programs like the African Network for Drugs and Diagnostics Innovation (Development)¹, the Alliance for Accelerating Excellence in Africa (AESA) developed by the African Academy of Sciences (AAS), and the New Partnership for Africa's Development ((AUDA-NEPAD)) Agency are African-led programs to support pan-African collaboration around scientific research and development (Simpkin, Namubiru-Mwaura et al. 2019). NEPAD

-

¹ Despite being sited in Simpkin et al. 2019 as a current program, a google search and review of the WHO-TDR website conducted in Feb 2021 revealed no documents or news appeared for ANDi after 2011

has a specific focus on integrating existing technologies, fostering research and breakthrough discoveries, training and developing a culture of science, and providing science and technology foresight through governance, regulation and ethics ((AUDA-NEPAD)). The Coalition for Research and Innovation (CARI) is a platform to build a collaborative regional and international donor community to support African-led R&D efforts.

Partnerships with high-income countries

"In an increasingly globalized world no one part of the world can operate in isolation" (Chataway, Chaturvedi et al. 2009). In looking to address concerns in LMICs' health sectors, innovation driven by need, supported through global public-private partnerships, with a foundation in a strong intellectual property system is a way forward (WIPO 2019). This need-first focus can then attract global partners with resources in funding and research.

Participants in international partnerships should be weary of incentives that could create an imbalance and inequitable partnership that might pull the agenda outside of Africa (Simpkin, Namubiru-Mwaura et al. 2019). Chataway et al., in their recommendations to African policy makers at NEPAD suggest that, building national health systems of innovation in Africa cannot be done in isolation and must make use of global and regional initiatives and partnerships to develop novel innovation pathways (Chataway, Chaturvedi et al. 2009).

York Zucci, Chairperson for the Centre for Unconventional Entrepreneurship and The Innovation Hub in Gauteng Province, South Africa, writes in his chapter in *Nuts and Bolts*, that

there are key basic building blocks for any organization, regardless of origin, looking to support innovators.

- Create your own support ecosystem that is tightly linked with the entrepreneurs you are trying to support. Make sure to support them along their entire path.
- Develop a close-knit community between entrepreneurs that you foster.
- Monitor the performance of each entrepreneur regularly and support them with subject matter experts.
- Access to networks is an innovator's biggest challenge. Open doors for them.

(Sibanda)

These are all factors that should be considered when creating partnerships to support innovation ecosystem development.

III. Conclusion

Innovation is a key driver and tool to achieve the Sustainable Development Goals. Specifically, global health is changing rapidly and must leverage innovation to address healthcare needs worldwide. For LMICs, that have historically been importers of innovation and technology, there is an opportunity and imperative to build innovative ecosystems to support the development of health biotechnology. Not only does a biotechnology ecosystem support economic development and job growth for a country, but owning a national or regional innovation agenda can ensure appropriate, contextualized research priorities and development to fit the local, contextual needs of the healthcare system. Africa lags behind other regions in the world in indicators of innovation and development in biotechnology while also bearing a significant portion of the global disease burden. Countries in Africa have taken a collaborative, largely pan-African approach to pooling resources and reducing barriers for a biotechnology ecosystem to begin to develop.

Organizations like NEPAD and APIRO aim to address key challenges facing this industry growth. International partnerships are essential to the development of innovation ecosystems to funnel funding, share knowledge, and build capacity from more mature biotechnology markets; however, these partnerships should ensure that the LMICs' leadership and research priorities are at the center of any arrangement.

While many initiatives are in place to support these goals of economic growth and reduced disease burden and drive collaborative initiatives, the continent as a whole remains disproportionately behind the world in research and development (R&D), knowledge retention, and intellectual property to support localized biotechnology innovation.

The case study of AHIA as a start-up training and consulting program fits into the larger literature of providing examples and lessons learned in the development of innovation ecosystems in Africa, specifically in AHIA's role an external partner to African-led innovation.

Chapter 3: Methods

I. Research design

A case study approach was used to document the start-up phase of AHIA's program evolution and its influence on the past three years of innovator participants. This approach was taken, in the absence of a formalized monitoring and evaluation plan for AHIA, to conduct an adequacy evaluation or larger impact report. This case study aims to 1) analyze the history of AHIA's programming and its participants and 2) provide key insights to inform the development of a theory of change and a Monitoring & Evaluation Plan to evaluate the program moving forward.

II. Collection of data and information

Five sources of data and information were used to compile and develop this case study: 1) AHIA program documents, 2) direct observations and experiences, 3) informational interviews with faculty and staff at Emory, 4) key informant interviews with student participants, 5) key informant interviews with former AHIA participants.

1. AHIA Program Documents

Due to the largely student-led operations for AHIA in the past three years, AHIA documentation was largely fragmented with no centralized database of historic information. As part of this project, data was consolidated from former AHIA staff coordinators (budgets, project plans), students (photos, notes, presentation decks), IT staff (media, logos, video) and AHIA leadership (business impact reports, grants, program materials) and placed into one shared drive. These documents provided background information for the evolution of the AHIA program, innovation descriptions of AHIA participants, and workshop objectives.

2. Direct Observations & Experiences

The first author's direct observations and experiences were used to develop this case. The first author participated as a student in the 2019 AHIA workshop and continued to work with a core group of graduate students to provide programmatic support and strategy recommendations to AHIA leadership through Spring 2020. In Summer 2020, the first author facilitated an innovative, digital project with a partner organization, AfricaBio, on behalf of AHIA and Emory University. She continued as General Manager for the AHIA program implementing digital programs, building connections, authoring grants, and advising the AHIA leadership board.

Observations and experiences as a student program participant and the AHIA manager inform the programmatic recommendations and analysis of the data. As part of the first author's manager role, numerous discussions with leaders in the biotechnology and innovation space in Africa were held. Conversations included a social impact accelerator, the first biotechnology venture capital firm in Africa, a South African Entrepreneur-in-Residence at Emory University, the president of AfricaBio, the president of AfriProspect and SheEquity, and multiple innovators from Ghana, Nigeria, and Zimbabwe. Additionally, to better understand the landscape of biotechnology innovation in Africa, the first author attended multiple virtual conferences and webinars including the BioAfrica Convention (August 2020), Financial Women's Association's Innovations in Healthcare Webinar (January 2021), Global Startup Grind Conference (February 2021), and MDG Boston's Maternal and Child Health Webinar (March 2021).

3. Informational Interviews with Emory faculty and staff

In order to understand the history of AHIA and the individual contributions of faculty and staff, informational interviews were conducted with AHIA leadership and key members of Dr. Dennis Liotta's staff who supported the AHIA program in various capacities. All interviews were hosted one-on-one via Zoom and focused on each member's individual contributions and perspectives on the AHIA program. In addition to AHIA participants, other members of the Emory community with a focus on innovation and biotechnology were interviewed. These included leaders from the Emory Biotechnology Consulting Club, Biolocity, The Hatchery, and the Goizueta Institute for Business and Society.

4. Key Informant Interviews- Students

While students were not a main focus of this case study, they do play a significant role in the AHIA program with 46 Emory students participating in AHIA workshops since 2017. Four students from the 2018 and 2019 workshops, along with personal observations, provided key insights and perspectives on the student experience in the AHIA workshop, directed study experience, and AHIA student-leadership year-to-year. Additionally, all 46 student participants were researched on LinkedIn to capture basic demographic, career, and educational information.

5. Key Information Interviews- Innovators

Twenty-one innovators have participated in AHIA since 2017. Due to lack of sustained program documentation, contact information has been lost on a majority of these innovators. For this study, each innovator was followed up on LinkedIn, a google search, or through their university's website to identify contact information and understand their innovation's progress since participating in the program. This information was gathered into a consolidated AHIA Innovator Directory. Of the 21 innovators researched, all but 2 innovators were found. Fourteen innovators were identified to reach out to on LinkedIn in order to request an interview on their AHIA experiences. The 14 innovators identified represented male and female participants, countries from each region of the African Union, and various types of innovations (health technology, diagnostics, therapeutics, devices). Eight innovators accepted the request for interview. All but one interview was hosted via Zoom and followed a qualitative interview guide (Appendix 1). One interview was conducted via WhatsApp due to inconsistent internet access.

III. Analysis

The first focus of analysis was to consolidate findings from the AHIA participant and student research and interviews prior to linking data across all sources to draw conclusions and

recommendations. Using LinkedIn profiles and google searches of participant's names, an AHIA Directory was developed to understand the key characteristics of AHIA workshop participants. Table 1 shows the data elements collected for participants. Key informant interviews with the AHIA innovators were documented using the interview guide format and findings were consolidated into three categories: 1) Strengths of the AHIA program, 2) Opportunities for program growth, and 3) Current needs as an innovator.

Table 2: AHIA innovator and student information collected

After this analysis, findings from the other data sources were used to better understand and contextualize the insights from the innovator interviews.

IV. Ethical considerations

Because this case study focused on developing a report on the AHIA program, it was not considered human subjects research and Emory IRB approval was not required. A non-human subjects research determination online questionnaire form was completed in February 2021. Innovators and students who participated in interviews were informed of the purpose of the interviews and that information from the interviews would be used in this report. All innovators gave verbal consent for interviews to be recorded with the exception of one. This interview was conducted over WhatsApp due to interrupted network connections.

V. Strengths and limitations

The original design of this research was an impact report on the AHIA program; however, without a formalized monitoring and evaluation plan to use as a benchmark, it was determined to take a case study approach to examining the AHIA program. As such, this case study does not allow for generalizability of programs to support biotechnology innovators in Africa; however, it does provide key insights to inform future recommendations for continuing and scaling the AHIA program, including the development of a formalized monitoring and evaluation plan. This case study, when combined with other writings on similar program implementations, can lead to a better understanding of the role of US-based universities and programs in supporting biotechnology innovation in developing countries including the limitations and strengths of such programs.

This case study leveraged limited and fragmented institutional documentation passed down year-to-year for AHIA. Gaps in documentation were filled through informational interviews with

AHIA faculty, staff, student leaders, and program participants. The first author was introduced to the AHIA program in 2019 and therefore relied on second- and third-party data to develop an understanding of the AHIA program prior to that date.

While the AHIA program aims to address unmet health needs in Africa, the program has not been guided by a global health methodology that incorporated key principles for program design, implementation, or monitoring and evaluation. For the past two-years, AHIA has been guided by loosely defined goals and objectives with no documented objectives or methods for evaluation which make evaluating and determining the formal impact of the program impossible. To mitigate the absence of this core documentation, a case study approach was utilized to inform the creation of a more formalized evaluation plan for AHIA as it moves from start-up to scale-up.

Chapter 4: Results

History of AHIA program

Emory University, based in Atlanta, Georgia, USA, is a globally recognized research and academic institute with a specific focus on healthcare and health sciences. With over \$831 million in funds awarded in 2020, Emory is designated one of the leading universities of research in the United States (Emory, 2021). Emory supports a top five infectious disease program and the second leading biomedical engineering program in the United States (Emory, 2021). The Office of Technology Transfer, which is responsible for supporting the commercialization of innovation at the University, boasts 18 unique areas of innovation from targeted cancer treatments, microsurgery support, gene therapy, screening tools, and vaccines. The Office has

supported 21 diagnostic/device products, 19 therapeutics, and 14 consumer/life science products from prototype to market (Emory, 2021). One of the largest biomedical innovation successes was the development of emtricetibine, a chemical compound used in HIV/AIDs therapy treatment developed by a team of chemists including Dr. Dennis Liotta.

In his own lab-to-market HIV/AIDs journey, Dr. Liotta went through numerous iterations of chemical compounds with many false starts. His team filed their first HIV drug patent for emtricetibine on Feb 1, 1990. In 2003, In 2005, Emory sold the royalties to emtricetibine to Royalty Pharma and Gilead Sciences for \$525 million (Transfer 2019). Today, in the US, over 90% of people living with HIV/AIDS have been prescribed a drug therapy that includes emtricetibine (Transfer 2019). Dr. Liotta continues to focus his research with the Liotta Group on discovery and development of novel therapeutic agents to address viruses, cancer, and inflammation. Dr. Liotta holds 89 issued US patents as of 2018 (Transfer 2019). He is the Director of the Emory Institute for Drug Development and co-founder of DRIVE, Drug Innovation Ventures at Emory, an affiliate nonprofit of Emory University (Emory 2019).

Dr. Liotta developed a passion to support biomedical innovation similar to his own lab-to-market journey. He, and a small group of multi-disciplinary faculty at Emory, have supported the training and mentoring of innovative biomedical scientists in Africa since the early 2000s. This team recognized that many of health biotechnology innovations get caught in 'the valley of death' trap, ie. where innovation is faced with infrastructure and funding issues that prevent it from reaching the marketplace. In connection with Emory and other world partners, the vision for helping innovators navigate this valley of death formed to provide business and legal training to scientists along with a

network to navigate these complicated pathways more effectively. Below is the vision as Dennis articulated it in his 2016 TedTalk in Geneva.

Over the past 15 yrs, I've worked extensively in Africa with Drug development scientists and entrepreneurs. I've seen firsthand the quality of their science and the passion they bring to diseases that affect their own local communities. So selecting Africa as the first target region for a worldwide initiative seemed obvious." (Liotta, 2016)

After connecting with African colleagues, a program called AHIA, Advancing Healthcare Innovation in Africa, formed. AHIA aims to leverage Emory's expertise in business, law, and biomedical commercialization to partner with industry leaders in the growing biomedical industry in Africa (AHIA 2021). The program has accomplished this through educating, supporting, and mentoring scientists and entrepreneurs with early-stage biomedical innovation in key areas of business and legal strategy. In its current operational form, AHIA is a start-up program. Since 2017, AHIA has supported 21 innovators across 10 African countries in medical devices, diagnostics, health technologies, and pharmaceuticals. Additionally, AHIA has provided cross-cultural learning opportunities for 46 Emory students from business, law, sciences, and public health to work with African scientists and innovators in collaborative, consultative projects.

Innovator Story

Maureen is a young, passionate scientist-entrepreneur from Uganda. In 2019, Maureen participated in Emory University's AHIA program, a 3-day workshop and optional semesterlong directed study to support early-stage bioinnovators in Africa. Maureen applied for AHIA

because she, along with a team of scientists from Makerere University, had developed a low-cost, practical device to address post-partum hemorrhaging in Uganda- a leading cause of maternal mortality, accounting for approximately 35% of all maternal deaths worldwide (WHO 2013). While their prototype worked, without backgrounds in business or product commercialization, the team did not have a pathway to move from their prototype to saving mother's lives in hospitals and clinics. Their innovation was facing many challenges common to early-stage entrepreneurs (business planning, funding, strategy, marketing) and unique to their regional context (lack of regulatory pathways, sparse funding, lack of manufacturing support). While they had applied for numerous other programs, they were often turned away because they were too early in their innovation journey.

AHIA teaches scientists and innovators, like Maureen, the basics of ideation, entrepreneurship, and intellectual property strategy to help them move to the next step of their entrepreneurial journeys. In an interview in 2020, Maureen said that "(Emory) was one of the best decisions that we've made as a company... AHIA helped us structure our innovation to understand the benefits of licensing, partnering, and networking. We gained a tremendous amount of knowledge packed into the 3 days and knowledge is power" (Etuket 2020). Fast forward to 2021 and Maureen is now a Nelson Mandela Scholar, her business received funding to conduct clinical trials, and she has sat on numerous global health panels to share her experience in healthcare innovation. One thing that Maureen is clear on is that innovation must be centered on local context and that 'African solutions must solve African problems" (Etuket 2020).

This mantra, 'African solutions to African problems', comes in the wake of decades of second-hand medical equipment shipped from more developed countries, a culture of Africa as an 'experimental sandbox', and African scientists not being seen as equal contributors to the global knowledge economy. And yet, scientists in Africa are uniquely positioned to create contextualized innovation for some of the world's largest health problems for the most vulnerable populations. There are many obstacles that face any innovator across the world from building the right team to securing financing. Innovating in healthcare makes this even more difficult with regulatory hurdles, intellectual property protections, and long timelines to include clinical trials. As a third hurdle, innovators from low-income countries in Africa have the additional burden of lack of access to R&D facilities, increased challenges accessing capital, incomplete or nonexistent regulatory pathways, bias against African-led companies, and immature intellectual property protections (Sibanda 2021).

Since the initial concept for AHIA was developed in the early 2000s, AHIA has aimed to support biomedical innovators in these challenging environments to bridge the gap from an idea in the lab to commercial success. After three years of running the AHIA program independently, AHIA took a step back in 2020 to better understand the structural barriers faced by biotechnology innovators and to understand the small impact that our program has had in addressing those needs. Through informational interviews with AHIA innovators who participated in AHIA from 2017-2019 and a literature review, we define AHIA's impact and key opportunities for a US-based, academic partner, like AHIA, to better programmatic support for creating an enabling environment for biotechnology innovation in Africa to thrive.

Advancing Healthcare Innovation in Africa

As a program of Emory University, AHIA aims to leverage Emory's own experience in developing biomedical innovation along with skills sets in international intellectual property, entrepreneurship, and public health research to support the still fledgling bio innovation

ecosystem by provide capacity building to support the unique needs of bio-innovators and build partnerships and programs to develop an enabling environment in Africa for these innovations to thrive. AHIA is a multi-disciplinary program of Emory University founded by Dr. Dennis Liotta (Laney Graduate School- Professor of Chemistry), Steve Sencer (Emory General Counsel), and Charlie Goetz (Goizueta Business School-

Mission

AHIA aims to address and solve unmet medical needs in Africa by supporting and promoting the advancement of health innovation and technologies. We do so by advising, educating, and training innovators in the business and legal aspects of the healthcare sector.

Professor of Entrepreneurship). Since its inception, additional faculty and staff from Emory School of Law and Rollins School of Public Health have joined the leadership team. AHIA's mission is to address and solve unmet medical needs in Africa by supporting and promoting the advancement of health innovation and technologies. We do so by advising, educating, and training innovators in the business and legal aspects of the healthcare sector. AHIA has operated under its current model since 2017 as a 3-day workshop for early-stage scientists and innovators in Johannesburg, South Africa. Emory students participate alongside innovators in the workshop and support market research, intellectual property and patent research, and help develop pitch decks. The top 2-3 innovators from each workshop are offered an opportunity to continue working with Emory students and faculty through a remote, semester-long directed study consultancy.

Over the past three years of hosting workshops, AHIA has seen innovations in diagnostics, medical devices, traditional medicine, and digital health from over 10 different countries in Africa. This report highlights the experiences of some of these innovators and student experiences to demonstrate the value of the program and recommend opportunities for strengthening the program in the future.

Evolution of the AHIA program

There have been a number of iterations of the AHIA program before its current form as a 3-day workshop with collaborative student support. At the center of each iteration is creating a network and opportunities for scientists to work with Emory's faculty in business, law, and sciences to advance their innovation. Figure 3 shows the timeline and evolution of related programs at Emory that have supported bio innovation in Africa.



Figure 3 - 10+ year evolutionary timeline of biomedical innovation training at Emory

AHIA & ANDi: 2015-2017

ANDi, African Network of Drugs and Diagnostics Innovation, was formed by the Special Programme for Research and Training in Tropical Diseases (TDR) in 2008 with a tagline of 'Health Innovation for Development'. ANDi's vision was to 'create a sustainable platform for R&D innovation in Africa to address Africa's own health needs". Specifically, ANDi aimed to achieve this mission by creating Centers of Excellence in drug discovery across the African continent (TDR 2011). This was in alignment with Emory's goals of building capacity in scientists based in Africa to develop contextualized biomedical innovations for diseases endemic to Africa and low resource settings.

A formal partnership between Emory University's AHIA program and ANDi began in November of 2015 under the direction of Dr. Solomon Nwaka, Executive Director of ANDi. The partnership aim was to create affordably priced drugs that address unmet needs of neglected diseases often ignored by larger medical corporations. This would be accomplished by teaching African scientists about the business and legal aspects of the bio-pharmaceutical sector including pharmaceutical development plants and intellectual property rights through a three day workshop in Johannesburg, South Africa. Participants were selected from the ANDi Centers of Excellence and Emory provided world-class faculty and an interdisciplinary team of Emory graduate students from law, business, and sciences to support the selected innovators in market research, business plan development, and identifying potential business partners.

Through this program outputs, the collaboration's goal was to identify one or more viable healthcare technologies to be commercialized with the support of Emory and ANDi's expertise and network. Of approximately three-dozen innovations that attended AHIA's workshops, three advanced to later stages. These innovations are listed in Table 3 below.

Table 3: 3 innovations that advanced from AHIA-ANDi workshops in 2015-16

Description	Value-add	Country	Partner	2018 Status
Exclusion-based sample preparation (ESP) applied to reducing the cost of viral load assay for HIV patients on antiretroviral treatment (ART)	Cost-saves, no refrigeration, reduced result time (14 days saved)	Uganda	Joint Clinical Research Center of Uganda University of Wisconsin	last update = identified potential African partnerships
ImmunoLine _{TM} , a rapid diagnostic test kit for detecting Rift Valley Fever	Faster and cheaper than current RDTs on the market; Economic savings from detecting Rift Valley Fever early (livestock)	Kenya	Kenya Medical Research Institute	last update = raising funds
Brilliance- Phototherapy device for neo-natal jaundice	Low-cost (\$300 vs industry standard - \$5,000)	Malawi	University of Malawi	ownership concerns, determining longevity

(Schaffner 2018)

Innovations were followed for the next year and recommendations made by the Emory team on establishing the innovator's next steps; however, in 2018, the partnership dissolved as ANDi leadership moved on from the program. The innovations were lost to follow up. Without ANDi, Emory did not have a guaranteed pipeline of innovators to train in the workshop or subsequent consulting programs nor a regional partner to provide ongoing support to innovators in their home countries. Starting in 2017, AHIA worked to develop its own pipeline to viable innovation in Africa to continue the mission of the program.

AHIA Present Day (2017-2019)



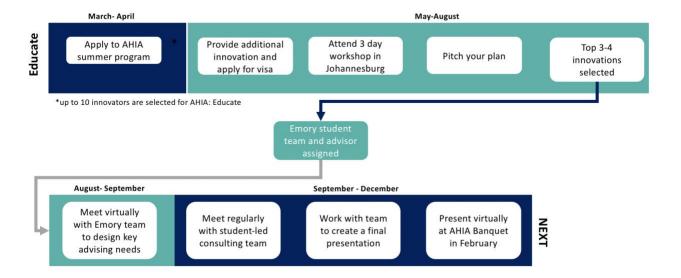
AHIA faculty, innovators, and students – 2019 workshop

Program overview and structure

Leading up to the COVID-19 pandemic in 2020, AHIA offered annual 3-day workshops for scientists and healthcare innovators in Africa and Emory graduate students. Currently, AHIA operates on a largely volunteer basis. Recruitment, workshop, directed study, and support activities were supported by students and faculty through 2020 (see program opportunities for more information). Figure 4 shows the innovator's journey and experience with AHIA through the workshop and directed study.

Figure 4: Innovator's journey and interactions with the AHIA program

Innovator's Journey with AHIA



Recruitment

Applications are distributed in March/April for innovators from eligible countries (must be able to conduct business in English and travel to South Africa) and Emory students across the disciplines of business, law, and science to participate in the workshop. In May, the AHIA leadership team and select Emory PhD candidates selected to attend the workshop review innovator applications and select the top 10-15 most promising innovations (viability of idea, feasibility, progress made to-date, responsiveness of innovator).

Workshop

In July, Emory students and professors travel to Johannesburg and meet the selector innovators.

Over the course of three days, students and innovators participate in interactive session that focus on the basics of business plan design, market research, developing a pitch deck, and protecting intellectual property. The students are divided into interdisciplinary teams that support the

innovators to conduct the research and deck development. At the end of each day, there is a round of presentations where each team presents their research and findings from that day's workshop. On day 3, the innovators give one final pitch to the professors and any guest lecturers.

Over the course of the next few weeks, an Emory student is selected to help facilitate a feedback survey and work with Emory leadership in selecting the top 2-3 innovations that leadership believes Emory support could be most valuable.

Directed Study

These three innovators are then sent an email offer to extend the AHIA relationship with a semester-long, student-led directed study project where a team of students will focus on a consultative project on behalf of the innovator to help them reach the next step. If the innovator determines there is value in the continued partnership, he/she will work with the student team through the Fall semester (August-December) supervised by Emory faculty. In February, Dr. Liotta hosts an AHIA banquet for the Emory students to celebrate the cohort and hear a final pitch and report on the innovations supported that year. If there are opportunities for further partnerships, those are discussed.

Aims and goals

AHIA aims to educate both innovators and students on the basics of entrepreneurship in the biotechnology space. This is important to expose innovators to a pathway to commercialization and for providing students the opportunity to work in a global, multi-disciplinary team.

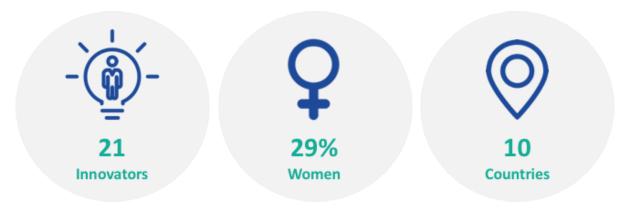
Goal: Foster the bio-innovation ecosystem in Africa to see low-cost, contextualized healthcare solutions to solve some of global health's largest challenges.

- Aim 1: Educate innovators in the basics of entrepreneurship and intellectual property to prove them a pathway to commercializing their innovations.
- Aim 2: Expose US-based students to working in cross-cultural, multidisciplinary team settings to become conscious global citizens and industry leaders.

One innovator shared that, 'seeing Emory University take the initiative to do this for Africa... is revolutionary. If you look at the structure of universities, there are few pathways to turning research into products. This program is very key for filling in some of these gaps for scientists from pitching to investors, understanding intellectual property strategy, and creating marketing plans."

Innovator Profile

Since 2017, AHIA has operated independently from partners and has solicited applications through social media outlets and innovator leads through contracts with organizations like BIO Ventures for Global Health (BVGH), a nonprofit based in Seattle, Washington that works at the intersection of public and private sectors to improve health outcomes through research (BVGH).



2021). In 2019, over 200 applications were received for the AHIA workshop. Since 2017, AHIA has supported 21 innovators from 10 different countries of origin across the African continent. Graph xyz shows the distribution of innovators. AHIA has hosted the most innovators from Nigeria (5), followed by Uganda (4), and Tunisia (3). AHIA pull is geographically diverse with representation from all continental regions of the African Union. Of the 21 innovators, 29% were female (71% male) and 11 of them came from a university or research institute setting.

Healthcare and Economic Promise

The innovators that AHIA supports address Sustainable Development Goals 03- Good Health and Well-Being, 06- Clean Water and Sanitation, 08- Decent Work and Economic Growth, 09-Industry, Innovation and Infrastructure, and 10- Reduced Inequalities. AHIA aims to ensure the promotion of women in science and innovation aligning with 05- Gender equality. Innovators represented a wide variety of sub-disciplines ranging from health technology to pharmaceuticals. The most prevalent innovation type was diagnostics (33.3%). Diagnostics ranged in assays to test for co-infections for HIV to rapid Diagnostic diagnostic tests for Rift Valley Virus, sepsis, and more. Health technology solutions were the second most prevalent. Technology Technology solutions addressed health delivery and water and sanitation. As an example, HelloMed was founded by a **Medical Device** businessman in Rwanda to alleviate overcrowding in hospitals **Pharmaceutical** and clinics. HelloMed provides at-home care and discrete

pharmaceutical delivery in the comfort of a patient's home in

Bioengineering

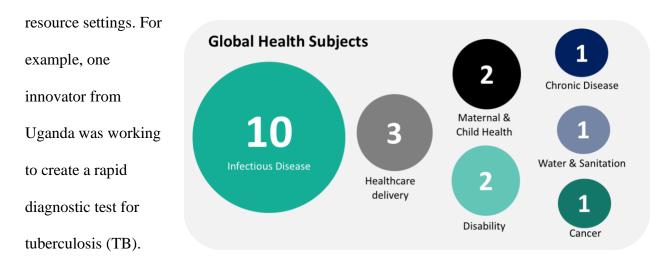
urban areas through use of a secure app. The technology solution leverages free capacity of doctors and nurses to connect professionals to patient needs. Medical devices addressed a number of global health topics from disabilities (low-cost 3D printed bionic arms; smart walking sticks) to a low-cost warp to address post-partum hemorrhaging.

Innovators focused on seven key areas of global health: infectious disease, healthcare delivery & system strengthening, maternal & child health, disabilities, chronic disease, water & sanitation, and cancer. Infectious diseases represented 46% of innovations. The focus of innovators reflects the disease burden on the continent and the priorities of innovators to solve problems they witness in their home countries. This echoes findings from Anne Pollock's anthropological study of iThemba, a drug discovery company in South Africa. In her interviews with scientists in South Africa, one scientist reflected:

"I think that it is important that people who are being affected are the ones who are doing the research. Because if you have seen someone suffer, you make all the effort to ensure that whatever you are doing gets out and ordinary people can benefit from it. You clearly understand the importance of doing it. Even people from other countries, they still understand, but the fact that it has affected you, you feel the strong need of intervention, the strong need of finding something that will be helpful and will be accessed in a cheaper way."

(Polluck 2019).

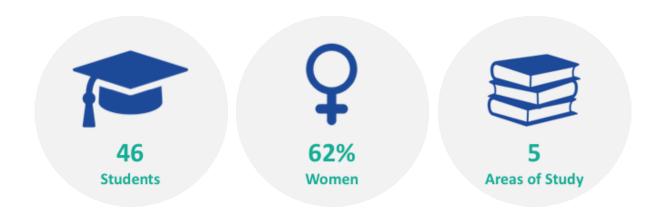
Many innovations also addressed the contextual needs of their healthcare systems. Common terms found in innovation descriptions included low-cost, sustainable, and for use in low-



Currently, the WHO-recommended diagnostic for TB takes, at a minimum, one day and lab equipment that is not easily accessed in rural communities. This can lead to loss-to-follow up to treat TB and continued spread of the infection in communities as patients wait for their results (Muwonge et al. 2014). Innovation to create a novel, rapid diagnostic test allows providers, specifically in low-resource and rural settings, to diagnose a patient on the same day they present with symptoms so that they can be isolated and treated more quickly.

While it was difficult to find specific information on company growth, there are multiple businesses built by AHIA innovators who have hired staff and secured additional funding. As an example, since attending in 2018, HelpMum, a Nigerian-based maternal and child health company, has grown from 1 to 10 employees and secured international funding from Google and Facebook.

Student Profile



There are advantages to students participating in global experiences during their education. Global experiences provide students the skill sets to work cross-culturally in an ever-globalized world. Students learn the importance of language, culture, and contextualized setting when working globally. However, in the US, only 3.4% of graduate students participate in a study abroad experience (Sanger and Mason 2019). At Emory, AHIA provides an opportunity for students to work across disciplines (business, law, science, and public health) and globally to understand the innovation experience in African countries. 46 students have participated in the AHIA program since 2017. Each year, at least two students continue to help run AHIA operations and prepare for the next year's workshop. 62% of students have been female, 38% were male.

Students come from both the undergraduate and graduate programs at Emory to form interdisciplinary teams that support each innovator attending the AHIA workshop. Beyond the cross-cultural, collaborative nature of the projects, students also learn from one another by interacting with different disciplines. Figure 5 shows the distribution of student degrees

including students who pursued dual degrees. The majority of students come from Emory's Goizueta Business School. These students bring knowledge and training in pitch development, market research, pricing, business model development, and strategy. AHIA also attracts students from Laney Graduate Studies which crosses all life sciences. Of the 11 PhD candidates who have participated in AHIA since 2017, a majority came from Immunology or another biological science. One student was an Environmental Health PhD candidate.



iteve Rogers -Emory MBA "My experience with AHIA has been absolutely stellar. I have lived and worked in several countries, but none compared to the type of experience I gained from this conference working with African scientist and mentors from Emory this past year. This conference gave me a well-rounded, multifaceted understanding of the difficulties faced for healthcare innovators to move from an idea and into a fully operational business. My favorite part of the program was working with an entrepreneur scientist on key methods of starting a business, including how to prepare a viable business plan."

AHIA 2018

For business school students, the experience allows them to learn about entrepreneurship in a different culture and apply their business skills in consulting, market research, and financial modeling to support the innovators. For some students, this exposure to working in a global setting with impactful purpose encourages them to explore social enterprise

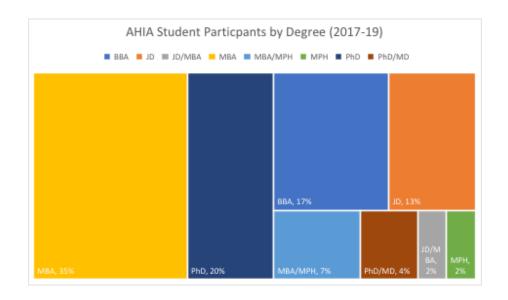
and impact-driven work. One student from 2018 who entered Investment Banking after completing her degree said that her work with AHIA was the most impactful experience during college. She plans to explore the social impact investing space as a result of her AHIA experience.

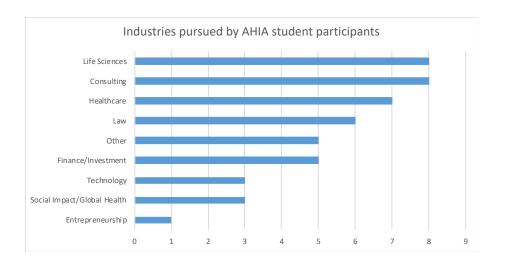
For PhD students, the AHIA workshop is often their first exposure to business concepts and entrepreneurship. They learn alongside scientific peers from African countries during the workshop and benefit from the collaboration with business students to develop pitch decks and a business plan. In 2019, one AHIA participant, a PhD in Neuroscience, fell in love with the intersection of



business and science. After finishing her dissertation in 2020, she joined McKinsey Consulting to pursue how to support scientific innovation through business principles. She credits her experience at AHIA in large part to defining this career path.

Tables 5 and 6: AHIA Student participants span a number of degrees and industries they pursued after graduation.





Key takeaways from the AHIA workshop

In Spring 2021, 9 semi-structured interviews were conducted with innovators who attended the AHIA Workshops from 2017-2019. Appendix Y shows the outline of the qualitative interview guide for these discussions. All interviews were recorded for internal use only and the innovators provided approval for any specific quotes to be used in the Impact Report. 15 innovators were contacted for interviews using LinkedIn and email. Of the 15, 10 responded for interviews with 9 being completed (2 interviews were rescheduled and lost to follow up).

All respondents noted that the AHIA workshop was beneficial to developing a pathway to advance their innovation. Each respondent provided different reasons that the workshop was beneficial to them and their business's needs. This varied largely on whether the innovator was a scientist, entrepreneur, or from a research institute.

Program Strengths

"If you are an innovator, it is important for you to have a vision that is clear and well-packaged.

This is a program that helps you shape that vision." (Etuket 2020)

Networking & people, intellectual property strategy, and business planning and strategy were cited as the three program strengths with networking being listed as a key strength for all innovators.

Networking & People- Each innovator interviewed stated that networks was a primary takeaway. For some, they found the networks that were opened up by participating in AHIA to be beneficial. For others, the peer-to-peer networking during the workshop with other innovators facing similar challenges in their home countries was invaluable to their learning experience. As one innovator put it, 'it was like speed dating in entrepreneurship. Very fast and intense." In half of the interviews, innovators mentioned specific Emory professors and students by name who impacted them. Two innovators specifically talked about inspiration. They benefitted from Dr. Liotta's transparency in his own lab-to-market journey. One innovator shared that, as a scientist, he had not understood the importance of working across disciplines to get his innovation to market. Hearing about Dr. Liotta's missteps, challenges, and failures in his journey was inspirational that the pathway to success is challenging, but doable and important to make a critical impact.

Intellectual property strategy- The second key take-away focused on the intellectual property training. Innovators learned to take copyright seriously, to protect innovation in order to scale it,

and provide strategy on how best to protect innovation based on your end goals and design. One innovator shared that, as a result of the AHIA workshop experience, he and his team now have two patents for their medical devices. This was not an easy feat as there is no regulatory pathway in his country nor are there intellectual property lawyers who could help them determine the right approach. "Since the program, we have filed 2 patents despite the challenges of finding an intellectual property lawyer in Cameroon. The program helped us think about protections on a global level" (Sokoundjou 2021).

Business planning and strategy- Multiple innovators mentioned that the overall workshop helped broaden their horizons and how they considered ideation, end user design, and marketing to build an effective business. One innovator stated, "Before the program, my team was made up of doctors and engineers. I was clueless about intellectual property or business" (Sokoundjou 2021). Another innovator pointed out that she learned how to ask the right questions when approaching potential partners. She points out, "knowledge is power. We saw this (AHIA workshop) as a knowledge-acquiring opportunity. Specifically, we learned how to break down a problem and translate our ideas and innovations into dollars and cents. We took away the important lesson of not innovating for the sake of innovation, but instead, to always design with the end user in mind" (Etuket 2020).

Opportunities for growth

Innovators also shared key opportunities to strengthen the AHIA program in the future.

Continuity- While innovators were largely positive about their experience at AHIA's workshop, they shared concerns around continuity and continued networking. One innovator summarized this sentiment well, "you (Emory) create a base but don't follow up with other resources, mentorship or coaching. There is no one available to follow up for outreach" (Akanji 2021). This criticism was echoed in a number of ways: lost contact with mentors and faculty, promise of creating a WhatsApp group that never happened, unclear expectations in the directed study offering. One innovator mentioned that at the end of the workshop, you need time to digest all the information that you have been given. Once you have time to do that, it leads to so many more specific questions about how to move forward that there is a need for additional guidance from the mentors and professors as you apply what you have learned into action. Another innovator, who successfully completed both the workshop and directed study, said that "you need people who believe in you and believe in the project". While she noted that she had a successful relationship with students during the directed study, there was no continuity with AHIA leadership and no one to reach out to for oversight, advisory, or expertise.

Cultural competency- Four innovators mentioned challenges with cross-cultural understanding. One innovator shared that, it was unclear what the AHIA program would pay for and what was expected to be covered by attendees. For instance, on the last night of the workshop, innovators and students decided to go out for a celebratory last dinner. While in the US, it is common to split the bill amongst the party if not otherwise stated, in many African countries, if you are invited to dinner, there is an expectation that the one who invited will pick up the bill. There was an awkward interaction at the end of the meal when the check came and not everyone had credit cards or the amount of cash needed to pay for meals. In the end, American students ended up

covering the cost of the whole meal; however, this was a situation that could turn into a teaching opportunity in cultural business practices and cultural norms.

Another innovator, who was selected to participate in the continued directed study, stated that "our partnership did not end well. They (students and professors) did not want to listen to how the solution would work in Nigeria as opposed to the United States". While this innovator was excited about the Emory partnership and expertise that the university and students brought to the table, none of the Emory participants or professors had cultural understanding of the innovator's country. The innovator recommended that "it is important for AHIA going forward that you give innovators the credit for knowing what will work in their own country. If you don't work here, you don't know" (Akanji 2021). This same sentiment was shared by another innovator who shared frustrations of how little contextual understanding the students had. He shared that his assigned student team was not open to learning or listening to his experience. "They didn't know the people that we were trying to design for. They had a curious disregard for wanting to know. There would be so much that they would learn if they spent even 6 months with us" (Dagadu 2021).

Location- Two innovators mentioned that it would be beneficial to host AHIA's workshops outside of South Africa. This was mentioned because:

1) if AHIA continues to source innovation from across the continent, there are visa restrictions for some people to travel to South Africa. This was encountered in 2019 with an innovator from Rwanda. He ended up completing the workshop remotely; however,

this significantly lessened his ability to participate and take advantage of networking opportunities and relationship building.

2) South Africa's bioinnovation ecosystem is the most developed on the continent, if AHIA caters to very early-stage innovation, why not host the workshop in locations who have less capacity building resources and support? Innovators specifically mentioned Kenya and Nigeria as potential locations due to the high level of entrepreneurship being developed in these countries.

Program design- Other feedback on the workshop itself included the following recommendations:

- Add a marketing professor to focus on market research and go-to-market strategies
- Provide more opportunities for innovators to network with one another outside of the multi-disciplinary student teams
- Create more time- it was short and rushed and did not provide enough time to apply the lessons learned
- Clarity on the goals and outcomes for students and innovators, what is the expectation for continued relationship. One innovator noted that her company was under the assumption that there was funding at the end of the program. No one followed up or provided clarity on how the engagement was supposed to end or what the expectations for next steps should be.
- Additionally, in interviewing select students who participated in the program, they
 mentioned that expectations of students and innovators was ambiguous. They shared that
 it was unclear if innovators were going to receive funding and what type of consultation

the students were going to provide. Innovators were disappointed to find that, after the 3-day workshop, the relationship with the professors and mentors was cut-off and no funding made available.

Innovator Needs

Each innovator was asked what their greatest needs as an innovator were today. This question was asked to help refine how the AHIA workshop is taught and also help inform what continuity and a continued relationship that AHIA might have with an innovation. Needs are summarized into three key buckets; strategy, funding, and credibility/visibility on a global stage.

Strategic guidance and consulting- Multiple innovators answered this question by discussing what their next big strategy hurdle is for their company. Questions that innovators are asking have to do with marketing, what are the right strategic partnerships for their growth model, how to scale manufacturing that cannot be accommodated in their home country, and how to make their product offerings culturally relevant as they scale to new countries. One innovator shared that he needed advice and support on whether to make his company's goal to sell to a global biomedical company or to keep going on his own.

Access to funding and funding strategy - "What innovators need most is funding". While, by and large, all innovators mentioned funding as being a crucial need, innovators were seeking more strategic advice on how to approach funding. For instance, one innovator made the decision to turn down a potential investment from a German Venture Capital firm because they wanted to do more on their own without an external party dictating their path. "We want to keep our funding

diverse and not get locked into someone taking too much equity" (Sokoundjou 2021). For an organization like this, mentorship and guidance on navigating funding pathways in order to reach their end goals is vital. This access to funding is echoed in innovator challenges shared by Dr. McLean Sibanda in his recently published book, Nuts & Bolts: Strengthening Africa's Innovation and Entrepreneurial Ecosystems, specifically for early-stage innovators looking to move from idea to proof of concept: "What has been frustration for many entrepreneurs is the lack of funding to develop ideas to proof of concept. In high income countries, such funding is provided by government grants and also angel investors- this is then followed up by venture capital funding and then private equity. There has been paucity for this type of development funding as well as venture capital funding available for entrepreneurs in Africa, though this is beginning to change." (Sibanda 2021). This is specifically of concern for the innovators that AHIA works with in biomedical innovation where larger investment is often needed to fund proof of concept. "The lack of proof of concept funding is a missing cog in the wheel of innovation and economic growth, not only in South Africa, but in many low-middle-income countries- more particularly in the rest of Africa." (Sibanda 2021).

Credibility/Visibility- A common theme among innovators centered around the need for credibility and visibility on a global stage. This was articulated in a number of ways. For some innovators without a scientific background, they wanted credibility from the global health industry to help validate their product offerings and evaluate their impact. Others talked about reducing risk to attract investors. One of the challenges faced by innovators is that many investors see ventures in African countries as risky due to economic instability and lack of familiarity. Additionally, two innovators shared bias and discrimination based on the race and

ethnicity. "There is a bias against African-led startups that can make it more difficult to receive financial backing. If the founder is white, we would have more money. Our competitors are based in the UK and in the US. They are able to get a different level of funding than I have been able to" (Akanji 2021). As such, these innovators were clear that they would not change their leadership; however, they seek to reduce bias and remove risk from a potential investment through partnerships with academic and research institutes, diverse board members, and participating in accelerator programs.

Networks and Long-term Partners- Tying strategic guidance, funding, and credibility together is the need for network and long-term partnerships. One innovator shared that her greatest need was a "consortium with a shared goal and the expertise to further develop the science that we have" (Burger 2021). Another innovator said that the continent needs partners to help facilitate networks to help innovation scale. As innovators reflected on AHIA's role, they all sought someone to believe in their mission, vision, and provide mentorship as they continued to grow.

Recommendations

There are key learnings that AHIA can use for re-imaging its programming as well as larger extrapolation for the role of global partners in supporting the evolving ecosystem of biotechnology innovation in Africa. As one innovator noted, "African problems can only be solved by African solutions, but we must have the support from the developed world" (Wayengera 2021). He also noted that AHIA could be uniquely positioned to bridge the gap between the private sector in the US and potential investors, like venture capital, to help fund intellectual property provisions and startup in Africa; however, the program currently does not

take full advantages of leveraging global networks between high-income countries and LMICs nor networks across disciplines needed to foster innovation ecosystems that support innovators.

As AHIA considers its future, there are four main recommendations to consider. Each of these incorporates feedback from the innovators on strengths and opportunities for the AHIA program, innovator needs, and review of the literature.

1. Define a key product type and stage of innovation that AHIA will support based on market research and assessment of Emory University's strengths and positioning.

Innovators recommended that AHIA develop a niche focus in the health biotechnology space due to the complexity of commercialization and the importance of networking within a specific research field. This is congruent with the research that shows current entrepreneurial ecosystems tend to not support the biotechnology industry well due to the complexity, timeline, and regulatory constraints on the sector (Sibanda 2021). AHIA should develop a key area of focus by understanding Emory University's strengths and positioning in health biotechnology and global health. Additionally, AHIA should explore analogous programs like Innovations in Healthcare at Duke University that are more established and that have developed their own focus in health technology and system strengthening. Finally, AHIA should consider the current landscape of health biotechnology innovation in Africa by conducting a needs assessment with organizations guiding the innovation ecosystem development. Organizations may include SanBio, AfricaBio, ARIPO, NEPAD, One Bio and more. Focusing on one type of innovation will allow the program to develop competencies in that area, develop appropriate networks, and create a cohort to promote valuable networks.

2. Design a theory of change, programming, and evaluation plan to support the defined focus area.

AHIA is an early-stage startup that has worked through various iterations of program development. What started as an idea between interdisciplinary faculty at Emory to teach entrepreneurship, has now developed into a capacity building program for early-stage scientists and Emory students. The innovative approach is in the cross-cultural program design to facilitate learning and drive further innovation. Without a monitoring & evaluation plan or defined aims, goals, and objectives, it is impossible to measure the program's success or potential for impact on capacity building or assisting scientists in advancing healthcare innovation in Africa. Once a core focus area is determined (recommendation 1), AHIA should design a theory of change, redesign its program, and create an evaluation plan to provide guidance, structure, and accountability to the program's larger vision. Social Entrepreneurship Accelerator at Duke University (SEAD) partners with a program called Innovations in Healthcare that supports healthcare social enterprises in LMICs. In 2020, SEAD published a report called Decoding the ABCs of Effective Enterprise Acceleration: 10 Lessons from the Social Entrepreneurship Accelerator at Duke (SEAD)(CASE 2020). The report outlines key considerations for a US-based organization looking to scale impact in healthcare. Learning from this report and other organizations, like Biolocity, a program of Emory University and Georgia Institute of Technology that supports early-stage biotechnology innovation from the two universities, can provide a basis for program design and scale for AHIA. This not only will allow AHIA leadership to measure success, but it will also provide better program structure, expectations, and follow through for innovators and students as defined as a key opportunity from the innovator interviews.

3. Engage in the health biotechnology ecosystem by participating in conferences, supporting research, and networking with partners to ensure implementation of best practices and expansion of opportunities for innovators and students.

As discussed in the literature review, the global health biotechnology is growing rapidly and increasing in LMICs as they seek to both grow their economies and address local healthcare needs through contextualized innovation. In addition, the recent COVID-19 pandemic has shone a light on the need for global health innovation across the world. In this rapidly evolving landscape, it is imperative for programs like AHIA to stay relevant with the latest developments impacting the health biotechonology ecosystem in Africa.

Conferences: AHIA should attend conferences that span start-ups (for example, Startup Grind), the biotechnology industry (for example, Bio Africa Annual Conference), intellectual property (conferences and webinars hosted by WIPO and ARIPO), venture capital, and entrepreneurship and innovation (for example, Unite for Sight's Global Health and Innovation Conference). By staying relevant in these areas, AHIA can better support innovators, design relevant programming with partners, and assist in opening doors for innovators to access other resources including mentorship, acceleration, funding, and more.

Membership networks: In addition to conferences, AHIA should explore memberships into network organizations such as The Aspen Network of Development Entrepreneurs, ANDE. Already AHIA has taken initial steps in this area by registering for an account in VC4A, a networking site to support entrepreneurs in Africa.

Research: As an academic university, one of Emory's core facets is research and scholarship. The area of health biotechnology in LMICs crosses over many sectors of global health, ethics, business, law, science, and technology. AHIA should consider research opportunities in partnership with Emory's schools and African Universities to foster multi-disciplinary research projects that align with AHIA's mission to advance healthcare innovation in Africa. As noted in the literature review and documented in innovator interviews, there is a need to support African researchers with credibility and visibility through international partnerships. AHIA should also look for opportunities to partner African innovators with research partners at the university in collaborative studies.

4. Engage with global education partners to develop a framework and curriculum to create AHIA's cross-cultural education component.

Most AHIA innovators noted concerns with cultural-humility among Emory students and faculty. Currently, there is no education provided to students regarding cultural-humility or the health biotechnology landscape prior to attending the workshop and partnering with innovators. This is a great concern especially since the literature shows a history of inequity in health innovation between partners from high-income countries and LMICs. Additionally, this does a disservice to Emory students who use the AHIA program as an educational opportunity to understand entrepreneurship and business in an international context. First, AHIA should work with Emory faculty who teach cultural-humility and international business to identify gaps and opportunities for improvement. Faculty may include professors in the Hubert Department of Global Health at Rollins School of Public Health who regularly work in multi-cultural settings

and who guide students in practices of ethics, cultural-humility, and global partnerships. Second, AHIA should consider a partnership with an African business school to explore cultural exchanges and provide an African-centric viewpoint on the health biotechnology industry, intellectual property, and entrepreneurship.

If these four recommendations can be addressed, AHIA has the potential to truly grow its vision of advancing healthcare innovation in Africa by supporting local, contextualized innovation. In order to achieve these recommendations; AHIA needs three main tools to organize and tackle the recommendations. First, AHIA needs an engaged board of directors from business, law, science, industry, investment, and public health. The board should include members with experience in LMICs, entrepreneurship and social entrepreneurship, intellectual property in Africa, and the biotechnology industry. A subset of board members should have extensive experience working in the African healthcare or biotechnology industry. Others should bring research backgrounds to help guide research opportunities and grant writing. Secondly, AHIA needs the strategic leadership and guidance of a Director. Currently, AHIA's operations are analogous to an earlystage startup with no full-time commitment. In order to carry out these recommendations and build the AHIA program, a full-time staff will be required to carry out the vision of the board and represent AHIA in all initiatives. Finally, AHIA requires additional funding to follow these recommendations. Conducting market research, developing programming, and seeking partnerships, especially with international partners will require a capital investment.

COVID-19 Opportunity

In March 2020, AHIA leadership was preparing to send out innovator applications for the 2020 AHIA workshop cohort. Due to COVID-19, the 2020 summer workshop was cancelled. This created new opportunities for AHIA to examine how else we could grow our AHIA platform and programming and begin to address some of the opportunities for AHIA in the future. In Summer 2020, AHIA developed a working relationship with AfricaBio, a bio-industry nonprofit based in South Africa that sponsors an annual BioAfrica conference to bring together bio-industry leaders from across the continent. Through this relationship, AHIA developed an online resource to support biotechnology innovators in Africa. What started as a focused effort on COVID-19 innovation (22 COVID-19 related articles were written by 7 participating Emory students) has now expanded into a platform to provide ongoing resources for biotechnology innovators in Africa. In Spring 2021, AHIA launched a webinar series focused on early-stage biotechnology innovators in Africa with the purpose of elevating innovator voices, creating an ongoing network, and providing credibility for AHIA innovators who previously attended workshops. Thus far, webinars have had up to 160 registrations for one event. Additionally, AHIA student leadership has worked to expand AHIA's network and conducted an informal listening tour with innovators, venture capitalists, consulting organizations, and thought leaders in the African innovation space to better understand the needs and challenges facing biotechnology innovators and how US-based organizations can best support the industry.

Chapter 5: Discussion and Conclusion

The AHIA program began with a vision to support early-stage African-led health biotechnology by leveraging the resources of Emory University. The program prioritized African-led partnerships to support this vision. Through the years and evolution of the program, however, structure and consistency to support this vision were lost as staff turned over and partnerships dissolved. For the past three years, there has not been a guiding monitoring & evaluation plan or clear expectations for the program's scope provided to innovators or to students. This case study reviewed documents and personal experiences with the program to understand AHIA's influence from 2017-2019 and provide recommendations for the future. Four key recommendations were made:

- Define a key product type and stage of innovation that AHIA will support based on market research and assessment of Emory University's strengths and positioning.
- Design a theory of change, programming, and evaluation plan to support the defined focus area.
- 3) Engage in the health biotechnology ecosystem by participating in conferences, supporting research, and networking with partners to ensure implementation of best practices and expansion of opportunities for innovators and students.
- 4) Work with global education partners to develop a framework and curriculum to create AHIA's cross-cultural education component.

As a university-based program situated in a high-income country working across cultures and industries, it is imperative for AHIA to have a structure and accountability for the innovators it supports and for the students learning from the experiential opportunity. In addition to the recommendations above, AHIA should not only consider program improvements to support individual innovators, but also partnerships with pan-African organizations to support and align

AHIA's programming with their work in developing a larger African health biotechnology ecosystem.

The health biotechnology ecosystem in Africa is developing through regional and pan-African collaboratives to pool resources and support developing regulations, policies, and investment in participating countries. There are incentives to support the growth of this sector to achieve SDGs, develop knowledge-based economies, and create contextualized innovation to prioritize the specific needs of LMIC healthcare systems and disease burdens. There is a tremendous market opportunity in the global health biotechnology industry if pan-African collaboratives fostering the grow of a health biotechnology ecosystem can find the right competitive advantage, incentivize research, and create advantageous investment opportunities. It is important that these efforts be African-led. Historically, collaborative global partnerships have shown a bias towards funding and research priorities defined by high-income countries. This has left a gap in Africanled research specifically focused on disease areas and health system problems endemic to many African countries. To change this, partners, like AHIA, from high-income countries should seek out African-led organizations with a clear mission and vision that can be supported with the resources global partners might have available, effectively shifting the power imbalance often found in global development partnerships.

If the 21 innovators educated through AHIA workshops are an indication, the future of health biotechnology innovation in Africa is bright; however, these innovators need support from all sectors. Continued research is needed to understand how current technology, focus on investment in biotechnology, intellectual property rights, and rapidly changing disease patterns might influence the development of health biotechnology ecosystems in LMICs. Additionally, beyond

research, innovators also need active partners willing to figure out the fragmented landscape alongside them. Programs, like AHIA, should aim to build collaborative, African-led partnerships to both support innovators and continue to work on a system level to develop an ecosystem that will allow innovators, regardless of their country of origin, thrive in the global health biotechnology landscape.

References

(AUDA-NEPAD), A. U. D. A.-N. (2020). Annual Report.

Akanji, A. A. (2021). AHIA Innovator Interview. B. Larkin.

ANDE (2021). "Member Map." Retrieved April 2021, from http://ande.force.com/.

Braithwaite, J., et al. (2018). "The future of health systems to 2030: a roadmap for global progress and sustainability." Int J Qual Health Care **30**(10): 823-831.

Burger, A. (2021). AHIA Innovator Interview. B. Larkin.

BVGH (2021). "BIO Ventures for Global Health." Retrieved March 10, 2021, from https://bvgh.org/.

CASE, F. B. S. (2020). Decoding the ABCs of Effective Enterprise Acceleration: 10 Lessons from the Social Entrepreneurship Accelerator at Duke (SEAD), Duke University.

Cerf, M. E. (2018). "The Sustainable Development Goals: Contextualizing Africa's Economic and Health Landscape." Glob Chall **2**(8): 1800014.

Chataway, J., et al. (2009). "Building the case for systems of health innovation in Africa." Science, technology and innovation for public health in Africa: 7-52.

CIA (2021). "The World Factbook." Retrieved April 5, 2021, from https://www.cia.gov/the-world-factbook/countries/.

Dagadu, S. (2021). AHIA Innovator Interview. B. Larkin.

Development, A. H. I. f. Strategic and business plan for the African Network for Drugs and Diagnostics Innovation (ANDi), WHO and TDR.

Emory (2019). "Dennis Liotta PhD." Retrieved April 4, 2021, from https://winshipcancer.emory.edu/bios/faculty/liotta-dennis.html.

Emory, A. (2020). Retrieved January 26, 2021, from https://www.ahiaemory.org/.

Erondu, N. A., et al. (2021). "Open letter to international funders of science and development in Africa." Nat Med.

Etuket, M. (2020). AHIA Interview B. Larkin.

Forum, W. E. (2019). Accelerating the Emergence and Development of Innovation Ecosystems through Procurement: A Toolkit, World Economic Forum.

Halla Thorsteinsdóttir, U. Q., Abdallah S Daar & Peter A Singer (2004). "Conclusions: prototing biotechnology innovation in developing countries." Nature Biotechnology **22**: DC48-52.

Harris M, W. E., Silver D, Macinko J. (2015). "'They hear "Africa" and they think that there can't be any good services'--perceived context in cross-national learning: a qualitative study of the barriers to Reverse Innovation." Globalization and Health.

Kansheba, J. M. P. (2020). "Small business and entrepreneurship in Africa: the nexus of entrepreneurial ecosystems and productive entrepreneurship." <u>Small Enterprise Research</u> **27**(2): 110-124.

Mumley, J. (March 30, 2021). "Health Business Investment in Africa". Retrieved April1, 2021, from https://ahb.co.ke/2021/03/30/health-business-investment-in-africa/.

OECD (2018). OECD Science, Technology and Innovation Outlook.

Palanica, A. and Y. Fossat (2020). "COVID-19 has inspired global healthcare innovation." <u>Can J Public Health</u> **111**(5): 645-648.

Pollock, A. (2019). <u>Synthesizing Hope: Matter, Knowledge, and Place in South African Drug Discovery</u>. Chicago, University of Chicago Press.

Salihu, H. M. and R. E. Azuine (2020). "Current and Emerging Issues in Global Health: An Introduction to Special Journal Collection." Int J MCH AIDS **9**(1): 1-3.

Santos, F. d. (2019). ARIPO: promoting innovation in Africa WIPO Magazine

Schaffner, A. (2018). AHIA: Advancing Healthcare Innovation in Africa Program Impact Report.

Sibanda, M. (2021). <u>Nuts & Bolts: Strengthening Africa's Innovation and Entrepreneurship Ecosystems</u>, Tracey McDonald Publishers.

Simpkin, V., et al. (2019). "Investing in health R&D: where we are, what limits us, and how to make progress in Africa." BMJ Glob Health **4**(2): e001047.

Sokoundjou, C. T. (2021). AHIA Innovator Interview. B. Larkin.

Soumitra Dutta, R. E. R., and Antanina Garanasvili, Bruno Lanvin, Sacha Wunsch-Vincent, Lorena Rivera León, Cashelle Hardman, and Francesca Guadagno (2019). The Global Innovation Index 2019, WIPO.

TDR (2011). "African Network for Drigs and Diagnostics Innovation (ANDI)." Retrieved March 7, 2021, from https://www.who.int/tdr/partnerships/initiatives/andi/en/.

Thorsteinsdottir, H., et al. (2011). "Health biotechnology innovation on a global stage." <u>Nat Rev Microbiol</u> **9**(2): 137-143.

Transfer, O. o. T. (2019). "HIV Antiretrovirals ". Retrieved April 3, 2021, from http://www.ott.emory.edu/about/success/HIV.html.

Wayengera, M. (2021). AHIA Innovator Interview. B. Larkin.

WHO (2013). Chapter 6. Priority diseases and reasons for inclusion. <u>Priority Medicines for Europe and the World 2013</u>, WHO.

WHO (2020). "World Health Statistics 2020: Monitoring health for SDGs." Retrieved April 5, 2021, from https://www.who.int/data/gho/publications/world-health-statistics.

WIPO (2019). Harnessing the benefits of IP for development <u>WIPO Magazine</u> World Intellectual Property Organization. **June 2019**.

Appendix

Appendix 1: AHIA Innovator Interview Guide

Purpose of this interview guide is to structure interviews with AHIA innovators who have completed the AHIA Johannesburg workshop in order to understand the type of innovators that AHIA has historically supported, track their innovation journeys to date, and solicit feedback on the AHIA program and continued support.

*request for recor	aıng
--------------------	------

Demographics-		
Name:		
Email:		
Phone number/Whatsapp:		
Linkedin:		
Gender:		
Country of Origin:		
Connected to a university?		
About:		
Innovation/Company		
Innovation/Company name		
(University Name if		
applicable):		
Year participated in AHIA:		
Did you participate in the semester	-	
long consultation?		
Please describe your		
innovation/business:		
Is your business/innovation still		
operational/in production? What		
stage is your business/innovation		
currently in?		
Business: Startup, pre-revenue,		
breakeven, profitable		

Innovation: Protype (what ve MVP, pre-launch, launch, acquired? Do you have any intellectual property (patent, copyright, provisional license, etc) for your innovation?	
Do you have external funding What type of funding?	g?
Team members: how many pare you working with? What their different roles?	
AHIA workshop experience	ro.
What were your main takeaways from the AHIA workshop?	
Did AHIA help you move your innovation to the next stage? If so, what was most helpful to you?	
Do you stay in touch with any students, faculty, or other innovators from your program?	
Where (in the program) is there an opportunity for AHIA to more effectively support innovators?	
Looking forward	
What is your greatest need a	s an innovator today?
How do you search for suppoinvestment, partnership, sub	
What are you currently work you headed next?	ing on and where are

Appendix 2: Innovator Spotlights

	Adereni Abiodun Akanji
er Country	Nigeria HelpMuM
Industry	Digital Health
Health Impact	Maternal & Child Health
Year	2018
Problem	Nigeria is the second largest contributor to the under–five and maternal mortality rate in the world (145 women/day). Every 10 minutes, one woman dies on account of pregnancy or childbirth in Nigeria.
Mission	Our mission is to eradicate infant and maternal mortality in Nigeria through the distribution of affordable Clean Birth kits to pregnant women in deprived and undeserved communities, registration of mothers on our vaccination tracking system, training of community birth attendants using our E-learning platform, and complete renovation of highly unhygienic and deteriorated state of community birth attendant homes.
Vision	To become Africa's leading mobile healthcare (mHealth) service provider before the year 2023. To see a world free of maternal and infant death.

Founder, Adereni Akanji, does not have a background in human health or maternal health; however, he saw a problem of high maternal mortality in Nigeria and wanted to be part of solving unnecessary maternal deaths. His solution, HelpMum, combines providing access to low-cost, hygienic birthing kits and digital health solutions to reduce overall maternal and child mortality in Nigeria and across the continent. When Akanji attended the AHIA workshop in 2018, HelpMum was still in an ideation and prototype stage. He was looking to gain advice on how to market, set up a sustainable business model, and then grow.

In reflecting on his AHIA experience, Akanji said that the workshop was valuable in proving access to other innovators from across Africa to network and learn from one another. He is still in touch with some innovators today. He also benefited from the intellectual property lectures as he considered new product innovation.

Today, HelpMum has grown to 10 employees. They have expanded service offerings to include a digital vaccine tracker, an e-learning platform, and health system infrastructure support

including access to electricity and hygienic transformation of traditional birth locations for safe deliveries.

HelpMum currently partners with corporate partners like Google and Facebook. Additionally, HelpMum has participated in programs like, <u>Disrupt Africa</u>. They are gaining media traction with features in <u>CNN Health</u> (2018).

As Akanji looks to the future, his greatest needs are in strategy support, partnership, funding, and validation. He is constantly considering, "How are we going to scale? Is our success in Nigeria specific to our context or can we scale to other countries in the region? What do we need to change or alter in our products to make them valuable for other countries like Ghana, Kenya, etc?" As he looks to scale solutions, he needs partners who can help him with research and developing a sound evidence-base.

To learn more, visit helpmum.org.

	Restrizymes
CEO/Founde r	Misaki Wayengera
Country	Uganda
Industry	Rapid Diagnostic Tests
Health Impact	Infectious Diseases (low cost, rapid test for use in rural communities)
AHIA	
Workshop	2018
Year	
Problem	The current standard time for many diagnostic tests, like TB, result to be
	received takes too long to treat many patients in rural communities. Samples are
	often taken from patients, travel to a centralized lab with the equipment to
	process the result. Results can take up to 7 days to produce. By that time, a
	potentially positive patient has returned home, exposed the community to TB,
	and may be lost-to-follow up, especially in rural, low-resource communities.
	This significant loss-to-follow up on TB positive patients results in the spread of
Mission	the disease and the inability to effectively treat patients.
WHSSIOH	To become masters of frontier biomedical research and innovation as a strategy
	to combat disease and enhance development. To achieve our goals, we invite participation of the affected communities, and partnerships with individuals,
	organizations (academia, industry, NGOs) as well as investors in development.

Vision	To become Africa's leading mobile healthcare (mHealth) service provider before
	the year 2023. To see a world free of maternal and infant death.

Dr. Misaki Wayengera was voted among the 100 Most Influential Africans in 2015 for his work in rapid diagnostic testing for Ebola and Marburg Viral Hemorrhagic Fevers. He founded Restrizymes to specifically look at innovative, low-cost, context-appropriate solutions for diseases endemic to Africa.

Previously, Restrizymes has received framework protection for an Ebola test (under WIPO) and has pursued protection for a Rapid TB Test under Uganda's Registration Bureau Services.

For more information, please visit www.restrizymes.net

Appendix 3: AHIA program evolution from 2007 (approx.) to Present

Years	Title	Program Description	Partnerships	Links and Articles
		Brings South African scientists to Emony and partner sites to receive advanced instruction in drug discovery disciplines.	ealth Institute	
2007	Emory South Africa Drug Discovery Training Program	The original program was funded by Emory's Global Health Institute and in partnership with a South African partner, NBF. They funded the travel of the scholars from South Africa and provided access to applicants. They did all the advertising in South Africa.	National Research Foundation-South Africa	Emory University Announces New Global Health Institute [Biospace, 2007]
2010-2013	Bioscience Leadership Program[1]	Prepare the next generation of life science leaders in emerging economies. Business plan and scholars program	Stellenbosch University	http://lead.eidd.emory.edu/
2000s-2015	Themba Pharmaceuticals	Received startup funds from the South African government via TIA (Technology Innovation Agency). Themba was a for-profit drug discovery company focused on treatment of TB, HIV, and malaria. Dr. Dennis Liotta participated on the elite international scientific board.	TIA	https://www.devex.com/organizations/Ithemba-pharmaceuticals-52567
				McLean Sibanda writes about his journey with the Innovation Hub in Nuts & Bolts, including a chapter on Emory's involvement
2012-Present	GAP Biosciences (Gauteng, Accelerator Program)[i]	Partnership with Goizueta Business Scool. Focused on a 1 week/year business training The Innovation Hub for scientists in Johannesburg		Korschun, H. (2012). "Educating entrepreneurs in South Africa: Emory partners to offer Gauteng Accelerator Programme." Retrieved 02/01/2020, 2020, from. https://news.emory.edu/stories/2012/03/gap_biosciences_south_ africa/index.html.
				https://www.theinnovationhub.com/innovation-programmes/gap- innovation-3
2015-2016	АНІА	The partnership aimed to train and mentor African science students, create technology incubators, provide technical support for pharmaceutical products	ANDI-Afrcian Networ for Drugs and Diagnostics Innovation Emory Institue for Drug Development	https://www.who.int/tdr/partnerships/initiatives/andi/en/
		Healthcare innovation at large. 3 day workshop that trains Emory students and African innovators in business and law basics to move their innovation to the next step.		
2017-2019	AHA[ii]	Student leadership from GBS begins to take over innovator outreach and providing programmatic structure (Morgan Bulloch 2017; 2018). Amelia Schaffner leads efforts to reach out to in-country partnerships for innovator recruitment.	completed by BVGH (BIO Ventures for Global Health)	https://www.ahlaemory.org/
2020	2020 AHIA	Due to COVID-19, the AHIA summer workshop was cancelled. Instead, we used the time to work on a collaborative early-stage concept for creating a Bio Africa Innovation Hub led by Africa Bio.	AfricaBio	https://mg.co.za/special-reports/2020-08-21-bio-africa-innovation- hub/

Appendix 4: AHIA Workshop Recommendations

In addition to the recommendations made for the larger AHIA program, there were additional recommendations made for the workshop itself including re-evaluating relationships with innovators and accountability and expectations.

Re-evaluate relationships with innovators:

One innovator advised to "invest in one success story to inspire a paradigm shift of investing in the knowledge-based economy in Africa". Currently, the longer engagement that AHIA might have with an innovator is 8-months. During this time, innovators have access to faculty for the 3-day workshop and a student team for up to 5 months. Based on innovator feedback, there is a need for a continued relationship or opportunities to ask que stions at a minimum; however, this cannot be managed or sustained without dedicated AHIA staff to facilitate communication and relationship-management between innovators and staff. Of the 9 innovators interviewed, all mentioned that follow-up and communication should be improved in the program.

AHIA should define and document clear expectations for participants on what the goals of the workshop are and what the role of AHIA will be in supporting innovators. AHIA should maintain ongoing relationships with innovators who participate in AHIA in order to track their success and needs. After the AHIA workshops, there should be opportunities for innovators and students to continue to interact and ask follow up questions for a period of time.

Accountability and expectations:

One of the unique value-adds of the AHIA program is the multi-disciplinary, cross-cultural experience for Emory students and innovators. This can create incredible value for all parties, if managed appropriately. In an increasingly globalized world, learning how to work in cross-

cultural settings is integral and vital. AHIA provides the opportunity for Emory students to learn from innovators about the challenges and opportunities in innovation within a low or middle-income country context. It is important to prepare students who have not traveled previously in how to be receptive to learning from different cultures and experiences.

AHIA should consider developing a curriculum for Emory students prior to the workshop to introduce concepts of international business, cultural-humility, and specific elements of African entrepreneurship, innovation, and health biotechnology to better prepare them for working with innovators. Additionally, AHIA should document and apply innovator and student descriptions for the workshop and directed study to set clear expectations for each participant. An example of this is seen below.