CDT AFRICA

Center for Innovative Drug Development and Therapeutic Trials For Africa (ሲዲቲ - አፍሪካ)

ANNUAL REPORT YEAR I

AFRICAN SOLUTION FOR A GLOBAL PROBLEM

Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa)
College of Health Sciences, Addis Ababa University

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ANNUAL REPORT
YEAR 1: 08 JULY 2017 – 07 JULY 2018

WORLD BANK GROUP

ADDIS ABABA UNIVERSITY

ACE II Eastern and Southern Africa Higher Education Centers of Excellence Project

IUCEA

CDT-AFRICA: BUILDING MEDICAL DISCOVERY CAPACITY IN AFRICA THROUGH EFFECTIVE PARTNERSHIP

MESSAGE FROM THE CHIEF EXECUTIVE DIRECTOR

It is with great pleasure that I write this message on behalf of the College of Health Sciences, Addis Ababa University, on the occasion of the release of the first annual report of the activities of the Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa), College of Health Sciences, Addis Ababa University. CDT-Africa is one of the three African centers of excellence (ACE) based in our university and one of five health related ACEs in the ACE2 project. The center is tasked with improving access to medicines (drugs, vaccines, diagnostics), and strengthening regulatory frameworks and healthcare delivery for Africa through relevant education and research. The mission and the work of the center is an indication of the commitment of the college to address the development challenges of Ethiopia and the region.

With the highest concentration of clinical specialists, basic science scientists, public health experts and the largest specialized hospital in the country, the college pursues excellence in education, research and community services and is an ideal platform for the work of CDT-Africa. Thanks to the remarkable dedication of our faculty and staff of the center and the full support of the college, this year has been a productive year for CDT-Africa. This is attested by the development of innovative MSc and PhD curriculums, training of hundreds of African scientists, expansion and consolidation of its work through new grants, and the establishment of partnerships with leading national and international institutions relevant to the work of the center.

The college will continue to support and shape the CDT-Africa as it moves from its initial foundational year to product-oriented development and expansion periods, particularly through the establishment of its new regional incubation hub in the coming year.

Thank you and I look forward to another productive year.

Dr Dawit Wondimagegne, MD

Chief Executive Director

College of Health Sciences

Addis Ababa University

Addis Ababa, Ethiopia

MESSAGE FROM THE HEAD OF CDT-AFRICA

When the Centre for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa) was conceived by the core team in 2015, it was a program whose time had come. The status quo was no longer tenable: Africa's virtual dependence on importation of medicines, with little to non-existent capacity for producing active pharmaceutical ingredients or novel products; extremely limited vaccine production capacity that threatens national security; import of most or all diagnostic reagents despite the relatively low technology requirement; and 80% of mortality caused by lack of access to essential medicines. The poor access to medicines is made worse by the fragile health system and weak regulatory capacity. All this translates not only into major health and security challenge for Africa but also that Africa would forfeit a major opportunity for prosperity. Underdeveloped human capacity, particularly the shortage of dedicated and specialized expertise, underlie the maintenance of the status quo. Although relevant infrastructures are weak or lacking, these can be built 'overnight' if there is a real prospect of producing the skilled manpower.

CDT-Africa was established as a formal center of education and research in the College of Health Sciences of Addis Ababa University under the World Bank funded Africa Centers of Excellence (ACE) project to tackle this formidable challenge. CDT-Africa has a comprehensive program of work to address this challenge. Drug, vaccine, diagnostics discovery and development are the core platforms and are supported by complex interventions and regulatory capacity to address the additional issues of system fragility. Capacity building focuses on skills-based short courses, masters and PhD programs led by research innovation. As a regional platform, CDT-Africa supports capacity building across eastern and southern Africa. We have assembled a cross-disciplinary team from all the four schools of the College of Health Sciences and other relevant colleges and institutes of Addis Ababa University and leading institutions and researchers across the world for the various components of the task. These partnerships offer unparalleled opportunity for making the center a world class hub for medical discovery and clinical translation. And this is the vision of CDT-Africa.

I would like to forward my sincere thanks to the College of Health Sciences leadership, headed by Dr Dawit Wondimagegn, for the support despite the challenges and uncertainties posed by innovative program like CDT-Africa. The admin team of the college at all levels, including the public relations team, has been extremely helpful. I would also like to thank the leadership of the university, particularly AAU president and his team and the former president of AAU. Line ministries, particularly the Ministry of Health, have been supportive. Very grateful to the local World Bank team and the team at the World Bank headquarters and the IUCEA. Our regional and international partners have been instrumental in what has been achieved in the past year. THANK YOU. The CDT-Africa core academic team has worked tirelessly with the only incentive of achieving the goals of CDT-Africa. Admin and technical staff of the CDT-Africa, including post-Docs--Big thank you for owning the vision and working continuously!

There have been few challenges on the way but we have learnt a lot through these challenges. The coming year is the most critical; we have more structures and support for recognizing and addressing the challenges more rapidly. I believe CDT-Africa has a genuine and substantive potential to bring about sustainable access to medicines and to act as a catalyst for bio-innovation more broadly if we can leverage the opportunities with a great sense of urgency. We have no illusion that the road ahead is "long and challenging but the desired objectives remain compelling and non-negotiable". May I take this opportunity to invite all and beyond with sincere humility to join us in this work.

Dr. Abebaw Fekadu, MD, PhD, MRCPsych

SUMMARY

The Centre for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa) was established as a regional hub for medical discovery (for drugs, vaccines and diagnostics) through the Africa Centers of Excellence (ACE) project with the support of the World Bank. Its establishment was motivated by the desire to address poor access to medicines across Africa.

The main aims of CDT-Africa are:

- Building sustainable endogenous capacity for medical innovation through education and training of scientists in partnership with leading higher education and research institutions producing the next generation discoverers.
- Discovery of new medicines for diseases underserved by current funding mechanisms and pharmaceutical R&D.

This report describes the key outputs and results of CDT-Africa in the past year:

- CDT-Africa has been administratively strengthened to support the day to day running of the center
- Has strengthened its regional and international partnerships through formal agreements and MOUs
- Has developed its first natural products database and is preparing to work on the first set of discovery research
- Has recruited 16 PhD students and 3 post-doctoral students working directly on medical discovery
- Has developed two skills-based, and first-in-Africa postgraduate programs targeting the issue of access to medicines directly
- Has trained over 130 scientists from Ethiopia and other parts of Africa through short courses (4-5 days long) focusing on vaccine discovery, diagnostics and drug development
- As a neglected tropical disease (NTD) and tuberculosis (TB) node, CDT-Africa is working to be a center of excellence in the diagnosis and treatment of NTDs and TB
- Has been transforming its phase 1 clinical trial unit into a clinical trial resource center
- CDT-Africa has attracted over $3.5 million as part of its effort to ensure sustainability

The potential and the opportunities presented by CDT-Africa are truly substantial, but the challenges are also huge. The academic milieu, the funding and investment ecosystems and the business and entrepreneurship environment have to change. CDT-Africa will advocate for changes but these issues have to be addressed in a systematic and organized way with input from those who have influence on institutional and national policy.

In the coming year, CDT-Africa will focus on education excellence, strengthening its incubation hub and on product development. CDT-Africa will work with key stakeholders to strengthen the investment and business ecosystems.

YEAR I

BACKGROUND:

The Centre for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa) is a World Bank supported Africa Center of Excellence (ACE) for education and research at the College of Health Sciences, Addis Ababa University (CHS AAU), Addis Ababa, Ethiopia. The main aim of CDT-Africa is to serve as a platform for equitable access to health interventions (medicines, vaccines, diagnostics and complex interventions) and bring about sustainable development in Africa through high-quality capacity development for medical discovery and bio-technology adaptation. The Center envisions to be an Africa-based, world-class canter for groundbreaking medical discoveries and development. Its priorities are to build endogenous sustainable capacity for therapeutic innovation through education and training of scientists who will lead medical discoveries, and to discover new medicines for diseases underserved by current funding mechanisms. Active work of the center has been since July 2017.

APPROACH:

CDT-Africa has taken a “Phased Implementation” approach to deliver on its program. These phases are naturally overlapping.

- Phase I (Preparatory) focuses on setting up all the administrative structures. The aim at the end of this period was to establish the key management structures of the Centre; to complete all the necessary maintenance and procurement tasks; finalize all collaborative agreements with the different institutions; and the objectives and strategies of the Centre agreed among all partners.
- Phase II (Early implementation), all curricula would be completed; database for natural products compiled and research begun; trainings begun; and program plan revised based on findings of this phase.
- Phase III (Full implementation), all activities of the Centre take place in full capacity; and internal and external monitoring and evaluation systems shaped the performance of the Centre throughout the fiscal year

At the end of the first year:

- CDT-Africa has been established as a formal center of education and research;
- Employed required staff and worked on strengthening the capacity of its staff;
- Strengthened partnerships through various meetings;
- Recruited PhD students in existing programs in line with its objectives and conducted several short terms trainings;
- Developed two major curriculums; and
- Worked successfully on initial sustainability plans;
- Has been awarded five new projects that support its aims.

The Centre has carried out mapping of medicinal products in the region, with the initial phase completed. It has also completed the first phase of the natural products database development. These outputs would facilitate relevant discovery, and innovation work and attract research and development investments and partnerships.

CDT-Africa has worked to strengthen its administrative capacity and conducted a number of relevant short-courses that support product development.

ACHIEVEMENTS

During this first fiscal year, the Centre embraced excellence as a core value and has made good progress.

1. ORGANIZATIONAL EXCELLENCE

With modest investment, the Centre established and setup its office (Figure 1) within the College of Health Sciences, Addis Ababa University (CHS AAU) at the beginning of the program. This involved refurbishing and partitioning of existing rooms, equipping office space, setting up information technology infrastructure, and creating organizational website (www.cdt-africa.org). The office is now fully setup with excellent internet access, and a reasonable reading area for visitors and PhD students. The staff are based in this new space since 05 January 2018.

Figure 1: CDT-Africa main office

The Centre held its first Consortium meeting on 23 October 2017 (Figure 2). The meeting fostered scientific learning and strengthened partnership.

Figure 2: Consortium meeting, 23 October 2017, Addis Ababa, Ethiopia

Representatives of CDT-Africa collaborators, including sector ministries, national universities, regional universities, national research institutions, international partners, and funding agencies attended the meeting (Table 1).

Table 1: CDT-Africa partner institutions that participated in its first consortium meeting in Addis Ababa, Ethiopia

Sector	Institutions*
Ministries Technology	Ministry of Health, Ministry of Education, Ministry of Science and
National Universities University	Mekele University, Bahir Dar University, Debre Tabor University, of Gondar, Jimma University
Regional Universities	Makerere University, Uganda; Mbarara University of Science & Technology, Uganda; Muhimbili University of Health & Allied Sciences, Tanzania; University of Malawi, Malawi; University of Zambia, Zambia
National Institutions	Armauer Hansen Research Institute (AHRI), Ethiopian Public Health Institute (EPHI), Food, Medicine and Health Care Administration and Control Authority (FMHACA), Addis Pharmaceutical PLC, Novartis, Ethiopian Medical Association
International Partners	King's College London, Brighton and Sussex Medical School, Harvard University, Program for Appropriate Technology in Health (PATH), African Union, Intergovernmental Authority on Development (IGAD)
Other	World Bank, World Health Organization

*Please note that, this has expanded while we were working to establish an incubation center

The Centre has employed key qualified staff to run its day-to-day activities and deliver on its key objectives, and mobilized potential associate members and visiting faculty to maximize productivity of the Centre (Table 2). The employees of the Centre have been in duty since 12 June 2017.

Table 2: Human resource composition of CDT-Africa

Staff role	No.	Academic qualification		
		PhD	MSc	BSc
Senior Faculty leadership/	8	8	-	-
Technical staff	3	1	1	1
Administration staff	3	-	1	2
Associate Members	10	10	-	-
Short-term employee	2	1	1	
Total	**26**	**20**	**3**	**3**

The Centre developed its five years strategic plan for the years 2017 – 2021, and its procurement manual approved by the World Bank and the AAU. Discussing with the Vice-President's Office of the AAU, the Centre secured dormitories for its regional PhD students. It is continuing discussions for additional dormitories.

The Centre signed memorandum of understanding with 10 of its partner institutions. The Centre conducted on-site visit to six national partner institutions to initiate collaborations and build institutional capacity of its partners.

The Centre established its own Scientific and Ethical Review committee composed of three members with the appropriate background. It also developed a Terms of Reference (ToR) to establish its Public Advisory Board (PAB) to be led by His Excellency Dr. Kebede Worku, State Minister of the Ethiopian Federal Ministry of Health (FMoH).

As part of its staff capacity development plan, the Centre sponsored travels of the Centre's Administrator to University of Cape Town in July 2017 to share experience on administration and project management. The Centre also sponsored travels of the CHS AAU Chief Administration and Business Development Director to participate on the ACE I technical advisory meeting held on 7 - 9 November 2017 in Accra, Ghana. Key faculty of CDT-Africa participated in the BIOINTERNATIONAL 2017 convention in San Diego over five days. This was an important opportunity to learn about global bio-innovations, how to develop young innovators and opened up crucial partnership opportunities. In this travel, the faculty initiated a link and partnership with Sanford Burnham Prebys Medical Discovery Institute (SBP) and University of California San Diego, particularly the Skaggs School of Pharmacy. The Centre was able to forge an important relationship with Bio-Ventures for Global Health (BVGH). CDT-Africa faculty also attended the first Africa-China-World Bank Higher Education Forum (July 9-14, 2017) in Beijing and Shanghai and got opportunities to share experience and to visit large technology hubs such as the Lenovo. Furthermore, relevant discussions were held with teams from the ACEs that work on natural and herbal products.

2. EDUCATION EXCELLENCE

The Centre initiated high quality education programs (Postdoctoral, PhD, MSc, and short courses) to build a critical mass of scientists and technical experts for medical discoveries. The Centre engaged its partner institutions to contribute to all its education activities, including in curriculum development, delivery of training, and participation as trainees.

2.1. Postdoctoral and PhD studentships

Until 07 July 2018, the Center enrolled a total of 19 PhD and postdoctoral fellows. The Centre enrolled 11 PhD fellows within the existing programs of CHS AAU in the 2017/2018 academic year. The programs are Pharmacology (4 fellows), Pharmaceutics (3 fellows), Microbiology, Immunology and Parasitology (1 fellow), and Mental Health Epidemiology (3 fellows). Four of the candidates are female with two from regional institutions.

The Centre enrolled two postdoctoral and three PhD fellows under its project implemented in collaboration with the Brighton and Sussex Medical School, University of Sussex, UK. Focuses of these fellowships are anti-infective agent's discovery, diagnostics, and complex interventions. One more postdoctoral and one more PhD fellows have been enrolled through the ASSET project.

The Centre provided technical and financial supports to three PhD research projects selected competitively. Recipients of this support are PhD students at CHS AAU whose PhD proposals have obtained ethical approval by the relevant ethical review committee and the PhD projects are in line with objectives of the Centre. Table 3 summarizes current postdoctoral and PhD students in the Centre.

Table 3: Postdoctoral and PhD students in CDT-Africa, 08 July 2018 – 07 July 2018.

Enrolment	No	Collaborating institution	
		College of Health Sciences, Addis Ababa University, Et	Brighton & Sussex Medical School, UK
Postdoctoral	2	-	2
PhD	14	11	3
PhD project	3	3	-
Total	**19**	**14**	**5**

2.2. Short-term trainings

The Centre has so far delivered four short-term courses (Table 4) in the fiscal year with the aim to maximize skills and critical thinking in research and therapeutic developments in its partner institutions. With these, 131 were trained and certified, of whom 30 (23%) were from regional (African) partners and 28 (21%) were female.

Table 4: Description of short-term trainings CDT-Africa delivered in the year 08 July 2017 – 07 July 2018.

Training	Medicines Dev.t & Regulation	GCP & Health Research Ethics	Vaccines & Impact on Human & Animal Health	Molecular Epidemiology, Diagnostics & genetic Engineering	Total
Participant	**N, %**	**N, %**	**N, %**	**N, %**	**N, %**
Total	26, 100%	41, 100%	23, 100%	41, 100%	131,100%
National	26, 100%	29, 71%	14, 61%	32, 78%	101, 77%
Regional	00, 00	12, 29%	09, 39%	09, 22%	30, 23%
Male	21, 81%	31, 76%	20, 87%	31, 76%	103, 79%
Female	05, 19%	10, 24%	03,13%	10, 24%	28, 21%
PhD/MD+	07, 27%	14, 34%	08, 35%	06, 15%	35, 27%
MSc	10, 38%	19, 46%	13, 57%	29, 70%	71, 54%
BSc	09, 35%	08, 20%	02, 08%	06, 15%	25, 19%
University	15, 58%	31, 76%	18, 78%	27, 66%	91, 69%
Gov. Inst.	05, 19%	10, 24%	05, 22%	11, 27%	31, 24%
Private Inst.	06, 23%	00, 00	00, 00	03, 07%	09, 07%

The Centre organized the first training, Medicines Development and Regulation, in collaboration with the Department of Pharmacology of the CHS AAU March 2018, and trained 26 participants. The training enabled participants (Figure 3) understand the philosophy and best practices in medicines development and helped identify challenges in drug development and the requirements for compliance with ICH GCP

using case-based approach and experience sharing. It also introduced the science and regulations pertaining to the development and review of new pharmaceuticals in developed countries (the U.S Investigational New Drug Application and the European Medicines Agency Clinical Trial Application) and in Sub-Saharan Africa.

Figure 3: Participants of “Medicines Development and Regulation” training held on 24-25 March 2018, Addis Ababa, Ethiopia.

The Centre provided the second training, Good Clinical Practice and Health Research Ethics, for five days, 11 – 15 April 2018, and trained 41 participants. The training equipped participants (Figure 4) with knowledge on principles of bioethics and concepts of good clinical practices in health research and responsibilities of stakeholders including, sponsors, clinical monitors, investigators, data and safety monitoring boards, institutional review boards/ ethics committees, and regulatory bodies in conducting clinical trials.

Figure 4: Participants of “Good Clinical Practice and Health Research Ethics” training held on 11 - 15 April 2018, Addis Ababa, Ethiopia.

The Centre organized the third training, Vaccines and Impact on Human and Animal Health, in collaboration with the Ohio State University, United States, delivered for five days, 11 – 15 June 2018, and trained 23 participants. The training informed participants (Figure 5) on the basic principles of vaccines (live vs. subunit vaccines, routes of delivery, adjuvants and delivery systems); factors affecting efficacy of vaccines (pathogen, environmental, and host factors); and impacts of animal vaccines for human health (zoonoses, safety and efficiency data).

Figure 5: Participants of “Vaccines and Impact on Human and Animal Health” training held on 11 - 15 June 2018, Addis Ababa, Ethiopia.

The Centre organized the fourth training, Molecular Epidemiology, Diagnostics and Genetic Engineering, in collaboration with the Ohio State University, United States, for five days, 18 – 22 June 2018, and trained 41 participants. The training provided participants (Figure 6) with an overview of core molecular approaches

relevant to diagnostics innovation. The course included core methods, including gene amplification, restriction, hybridization, genotyping, genomics and gene cloning procedures; analysis and interpretation of genotypic data; and practical applications in public health.

Figure 6: Participants of "Molecular Epidemiology, Diagnostics and Genetic Engineering" training held on 18 - 22 June 2018, Addis Ababa, Ethiopia.

2.3. New MSc and PhD curriculums

As part of its commitment to support regional capacity for health innovations, the Centre developed a new Master's curriculum in Clinical Trials, the first of its kind in Ethiopia and the Region. The Center designed the curriculum for the training of experts who are actively contributing to the clinical trials process in Africa. The program's overall aim is to prepare competent individuals who would work in pharmaceutical industries, regulatory agencies, contract research organizations, academia and other research centres, with the primary objective of assisting with the designing, execution and reporting of clinical trials pertaining to drugs, diagnostics, behavioural interventions and medical devices commensurate with good clinical practice, legal, ethical, and regulatory requirements. Development of the program followed standard procedures, including needs assessment. Analysis of the needs assessment survey (Table 5) confirmed high need for the program to improve access to interventions in Africa and accelerate regional development.

Table 5: Findings from needs assessment survey of MSc in Clinical Trials curriculum

Characteristics		**n**	**%**
Gender	Male	19	76
	Female	6	24
Qualification	MD+ (MSc/PhD)	6	24
	PhD	4	16
	MSc/MPh	12	48
	BSc	3	12
Institution	NGO working in health	1	4
	Pharmaceutical company	2	8
	University/research institute	21	84
	World Health Organization	1	4
Experience in clinical trial	Yes	9	36
	No	16	64
Barriers for conducting CT	Resources	24	96
	Trained leaders	23	92
	Regulatory system	17	68

	Knowledge	11	44
Importance of Africa CT network	Very important	25	100
Importance of CT in therapeutic development	Very important	25	100
Importance of expert leaders	Very important	25	100
Importance of MSc in CT for CT	Very important	24	96
	Important	1	4

The Center conducted a curriculum validation workshop of the MSc curriculum and reviewed the curriculum further to incorporate comments and suggestions captured in the validation workshop. The Center advertised the new MSc in clinical trials and received over 500 applications, of which top 26 obtained preliminary acceptance for enrollment in the coming academic year beginning October 2018.

The Centre developed a new PhD program in Translational Medicine aimed at developing scientists with the appropriate knowledge and skills for designing, developing, and delivering medical solutions – vaccines, diagnostics, drugs and other interventions. The role of these scientists will be an expanded one, which will include developing new vaccines, drugs, diagnostic and screening assays, adapted diagnostic methods, and therapeutic interventions. The development of the curriculum included input from regional and international partners, and involved a two days development workshop (27 – 28 January 2018) with experts in all the key tracks of the program (Figure 7).

Figure 7: Some of the participants of the curriculum development team who took part in the workshop held on 27 – 28 January 2018, Bishoftu, Ethiopia.

The Centre undertook a need assessment survey (Table 6) of the PhD program, where 51 participants from Ethiopia (62.7%), other African countries (25.5%), and Europe and the US (11.8%) filled the questionnaire. All participants supported the PhD program in Translational Medicine and indicated that a PhD program focusing on development of vaccines, diagnostics and drugs was very important and that it would address the substantial gap in improving access to novel and established products.

Table 6: Findings from needs assessment survey of PhD in Translational Medicine curriculum

Characteristics	(n = 51)	n	%
Country	Ethiopia	32	62.7
	Other African Countries	13	25.5
	US/Europe	6	11.8
Qualification	PhD	14	27.5
	MD+ Specialization	12	23.5
	MSc	21	41
	BSc	4	8
Institution	University/research institute	45	88
	NGO working in health	4	8
	Government Ministry/ healthcare	2	4
Gender	Male	36	71
	Female	15	29
Importance of program that supports vaccine development?	Very important	44	86
	Important	6	12
	No opinion	1	2
	Not important	0	0
Importance of program that supports diagnostic development?	Very important	45	88
	Important	5	10
	No opinion	1	2
	Not important	0	0
Importance of program that supports drug development?	Very important	47	92
	Important	4	8
	No opinion	0	0
	Not important	0	0
Importance of establishing PhD program in TM?	Very important	42	82
	Important	9	18
	No opinion	0	0
	Not important	0	0

Further curriculum validation workshop was conducted with 43 participants from Ethiopia and Africa (Figure 8). The PhD curriculum document was further reviewed to incorporate comments and suggestions from the validation workshop. The Centre submitted the curriculum to the Academic Standards and Staff Affairs of the CHS AAU on 06 May 2018 and has obtained important comments. The Centre accommodated the comments and submitted a revised version of the curriculum for the office for approval.

Figure 8: CDT-Africa PhD curriculum validation workshop, 15 April 2018, Addis Ababa, Ethiopia

3. RESEARCH EXCELLENCE

3.1. New research grants

The Centre has secured five new grants in the past year to be implemented over the coming 4-5 years, with a total generated grant coming to CDT-Africa of over $3.5 million. These grants have the potential to advance innovations and harness knowledge transfer. The Centre launched the five projects officially on 20 June 2018 with its partners (Figure 9), while implementation of the projects has started since January 2018.

Figure 9: CDT-Africa five projects launch ceremony (Dr Anteneh Belete, Director of Research and Technology Transfer & Training Lead of CDT-Africa speaking on the occasion), 20 June 2018, Addis Ababa, Ethiopia

Details of the five projects are as follows:

EXIT-TB : Translation research into policy and practice: Scaling up Evidence Based Multiple focus Integrated Intensified TB Screening to End TB in the East African region-This multi-centre implementation study aligns with the diagnostics platform of CDT-Africa. The project aims to improve detection of TB through integrated and intensified TB Screening package. In addition to Ethiopia, the project involves four African countries: Tanzania, Kenya, Uganda, and Sudan. Implementation of the intervention package is in four urban and three rural facilities in each participating country. The implementation will lead to a stepped

wedge clinical trial. Expected outcomes of the project include increased TB case detection, reduced TB diagnostic and treatment delays, and increased number of TB patients put into TB care including women and children. Linked to this project, CDT-Africa is a TB node, and will work to be a centre of excellence for the diagnosis and treatment of TB. The European and Developing countries Clinical Trials Partnership (EDCTP) funds the project with €2,957,924.09 for a total duration of 36 months. The project will recruit one PhD student. CDT-Africa's Clinical Trials Lead is the Principal Investigator of the project for Ethiopia.

PROFORMA : Pharmacovigilance infrastructure and post-marketing surveillance system capacity building for regional medicine regulatory harmonization in East Africa. This project aims to strengthen regulatory capacity on pharmacovigilance (PV), which strengthens the regulatory platform of CDT-Africa. It plans to assess current PV policies, regulations, and infrastructures; introduce comprehensive intervention programs and good PV practices; generate cohort of PV trained staff working in national regulatory authorities; and provide Interregional training of trainers' course on PV. It consists of six work packages to execute in collaboration with the Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA). Expected outcomes include National PV infrastructure, post-marketing surveillance and regulatory capacity for clinical trial safety data management; a cohort of PV trained manpower generated; twelve advanced trained personnel (4 PhD and 8 MSc) on top of those getting short courses both in-country and abroad in PV; provision and adoption of PV tools and technical support in adverse drug reaction reporting system; and PV networking among regulatory authorities, universities and international collaborators. The project is a consortium of six countries, namely Sweden, the Netherlands, Ethiopia, Kenya, Rwanda and Tanzania. EDCTP funds the project with €3 million for a total duration of 60 months. CDT-Africa's Deputy Head is the Principal Investigator of the project for Ethiopia. The overall Principal Investigator, Professor Eleni Aklilu, is a key member of CDT-Africa. Collection of baseline assessment has already been done, and TOT on MDA and HPV post campaign PV has been conducted.

EnDPoINT Consortium : Integration and scale up of care package for patients with lymphoedema in Ethiopia. The project aligns with the drug development, diagnostic development and complex interventions platforms of CDT-Africa. The project is a collaborative undertaking of CDT-Africa and the Brighton and Sussex Medical School, UK. The 3 main focus areas include: (1) development of anti-infective and anti-scabies topical products (which will evolve into skin care product development); (2) Diagnostic development focusing on techniques for diagnosing lymphedema at an early stage; (3) Complex intervention, which aims to integrate and scale up a holistic package of community-level care, including physical and psychosocial care, into government-run health services for patients with lymphedema, specifically podoconiosis, lymphatic filariasis and leprosy, in selected districts in Ethiopia. The first study has begun with collection of data on natural products and establishment of a database. The first part of this database has been completed with new partners to help with the work identified. The diagnostic package is under development with partners from BSMS and Georgia Tech. The complex intervention study has three phases, and the work has began in partnership with the Amhara regional health bureau and the Awi zone in Ethiopia. The UK National Institute of Health Research (NIHR) funds the project for a total amount of £805,052. CDT-Africa's Centre Head is the Principal Investigator of the project. The overall lead of the project, Prof Gail Davey, leads the partnership of CDT-Africa with the BSMS and University of Sussex.

ASSET : Health system strengthening in sub-Saharan Africa. The project aligns with the complex intervention and diagnostic development platforms of CDT-Africa. The project is a collaborative undertaking of CDT-Africa (CHS AAU), Ethiopian Federal Ministry of Health, King's College London, and the University of Cape Town. A successful implementation of the study will address the issue of health system fragility and will also offer a new life saving blood pressure equipment (CRADLE). The complex intervention aspect of the research aims to develop effective health system strengthening interventions to support the translation of clinical evidence into delivery of integrated continuing care at scale across healthcare platforms for Non-communicable diseases, mental and substance use problems, surgical and dental care, and maternal healthcare in Ethiopia. The project receives funding from the NIHR for £1,108,223. CDT-Africa's Complex Intervention Coordinator is the Principal Investigator of the project for Ethiopia. The overall lead of the project, Prof Martin Prince, leads the partnership of CDT-Africa with King's College London.

EACCR2 : East Africa Consortium for Clinical Research. This project aims to establish a new node (NID) to manage and establish the needed facilities to conduct clinical trials on neglected, emerging and re-emerging disease that burden the region. Through this program, CDT-Africa will be established as a clinical trial and clinical research node for neglected tropical diseases, particularly leishmaniasis and malaria. The project intends to boost and deliver an Eastern Africa training and mentorship program promoting an increase and retention of the independent African researchers, research leaders and managers to conduct internationally competitive clinical trials. It also plans to strengthen and strategically expand South-South and North-South collaborations between researchers and institutions with a specific focus on supporting less established Eastern Africa institutions in building capacity for conducting high quality clinical research. It has five work packages that leads the projects to strengthen the collaboration and optimize the use of shared research infrastructures and other capacity-building resources and opportunities. Implementation of the project is by a consortium consisting of 23 institutions from Uganda, Ethiopia, Kenya, Tanzania, Sudan, Rwanda, Belgium, Sweden, UK, and the Netherlands. EDCTP funds the specific NID project with €42,000 for a total duration of 36 months. CDT-Africa's Diagnostics Lead is the Principal Investigator of the project.

3.2. Strengthening and promoting clinical research

The Centre expanded capacity of the phase I clinical trials unit at the CHS AAU. Visiting some clinical trial centers in Ethiopia (Figure 10) and bringing experts together, the Center studied and identified infrastructure and material needs of the Unit.

Figure 10: CDT-Africa Leadership and Staff at DNDi Leshmaniasis Research and Treatment Center visiting clinical trials, 27 February 2018, University of Gondar, Gondar, Ethiopia.

The Centre is currently conducting modest renovation and procuring equipment and supplies (Figure 11) to advance capacity of the Unit to meet optimum standard. Preparation of standard operating procedures and trial forms are underway.

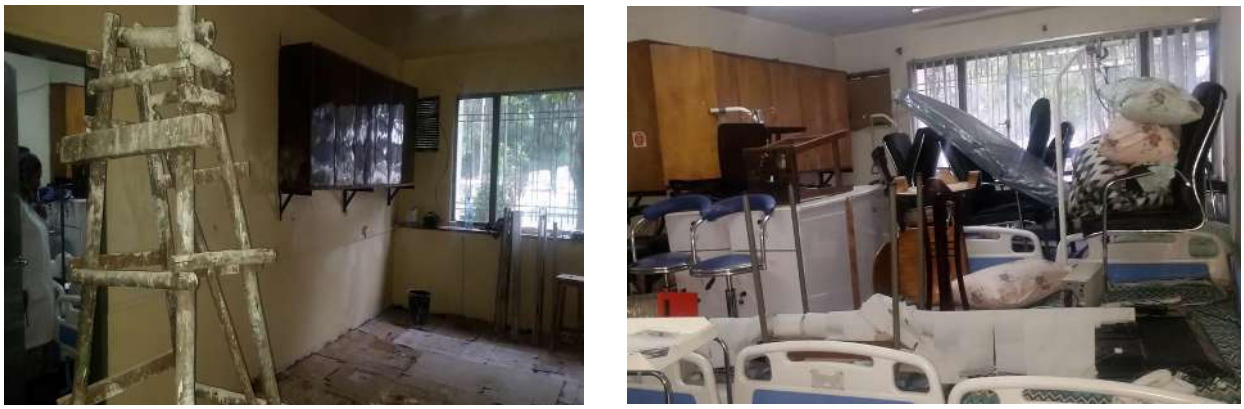

Figure 11: CDT-Africa renovating and equipping Phase I clinical trials Unit at CHS AAU

The Centre initiated a platform to launch its Incubation Center for Biomedical Innovation. CDT-Africa team had undertaken discussions with the management of the CHS AAU, State Minister of the FMoH, and scientists within and outside the AAU for additional inputs. Development of a proposal for establishing the incubation center is in progress.

The Centre organized and hosted scientific events to promote clinical research and clinical trials capacity and scientific activities. It led the celebration of the 2018 International Clinical Trials Day (ICTD) on 21 May 2018 (Figure 12) and the 2017 ICTD on 24 October 2017 (Figure 13).

Figure 12: International Clinical Trials Day celebration, 21 May 2018, Addis Ababa, Ethiopia (Dr Dawit Wondmagegn making an opening remark on the occasion).

Figure 13: International Clinical Trials Day celebration, 24 October 2017, Addis Ababa, Ethiopia.

The Centre co-organized with CHS AAU and the Medical Education Partnership Initiative (MEPI) the 2017-18 CHS Annual Research Day held on 22 May 2018 (Figure 14).

Figure 14: 2017-18 CHS Annual Research Day, 22 May 2018, Addis Ababa, Ethiopia (Prof Zerihun Woldu, Vice president for Research and Technology Transfer, reading the posters on the research day)

The Centre organized various guest lectures to promote knowledge exchange between external scientists and the CHS community in areas relevant to the aims of CDT-Africa. Among these were “personalized medicine in cancer treatment” and “pharmacokinetic optimization of cancer treatment” given by Prof Moustapha Hassan, a Professor of Experimental Hematology and Experimental Cancer Medicine, and Dr Alan Fotoohi, a Consultant Clinical Pharmacologist, respectively, from Karolinska Institutet, Sweden (Figure 15), held on 29 March 2018, at CHS AAU.

Figure 15: Guest lecturers from Karolinska Institutet, Sweden, one of the Knowledge partners of CDT-Africa and CDT-Africa team, 29 March 2018, Addis Ababa, Ethiopia.

The Centre organized a launch event for a Lancet Commission report on the future of health in sub-Saharan Africa (The path to longer and healthier lives for all Africans by 2030: the Lancet Commission on the future of health in sub-Saharan Africa) held on 14 September 2017 at CHS AAU (Figure 16), participants discussed on the role of CHS AAU towards harnessing care and biomedical innovations to contribute to longer and healthier lives for all Africans by 2030. CDT-Africa had contributed to the report.

Figure 16: A Launch event of a Lancet Commission report, in which CDT-Africa contributed, 14 September 2017, CHS AAU.

3.3. Preliminary studies

Conceptualizing Center of Excellence. The Center conducted a study to understand the key features of centers of excellence, particularly in relation to higher education and research, and on the mechanisms to ensure their sustainability. It conducted a scoping review of scientific and grey literature coupled with exploratory data from focus group discussions held with Leaders of Centers of Excellence in Africa.

Analyzing the findings, the Centre articulated a conceptual framework for a self-sustaining center of excellence for research and education in Africa.

Establishing natural products database. The Centre conducted a preliminary study of natural products that are traditionally in use by communities in Ethiopia and for which preliminary (pre-clinical data existed). The study produced a database of 200 natural products, of which 44 progressed for further evaluation of their anti-effective properties through pre-clinical and clinical studies.

Medicinal Products mapping. The Centre conducted mapping of medicinal products with the main aim of mapping key resources for medicinal products and other interventions within Ethiopia and the East Africa Region. Such resources included pharmaceutical companies, medicinal products produced, level of accreditation, internationally accredited laboratory facilities, bioequivalence units, clinical trial programs, accredited ethics boards. The Centre is currently compiling the report.

Studies at proposal stage. The Center produced one research proposal on natural medicinal plant to conduct pre-clinical investigation of its safety profiles.

3.4. Publications

In the reporting fiscal year, the Centers faculty published 56 research articles in reputable peer-reviewed journals also indexed in PubMed.

The Centre contributed to the ACE II Newsletter published on May 2018, where it demonstrated its commitment to ensuring sustainability of the program through new grants (https://ace2.iucea.org/ACEII-Newsletter.pdf).

CONCLUSION:

In its first fiscal year, CDT-Africa has laid the essential foundations and has evolved as a potential contributor to medical discovery and development in Africa, with more geographical diversity and greater inclusion of global stakeholders. Despite the key achievements in this first fiscal year, the key capacity building work is yet to begin. To support this, we aim to initiate a new PhD focusing on skills based product development, which is in approval process. We also aim to run related post-doctoral program and establish a new bio-incubation hub this coming fiscal year. We see no alternatives but to build a critical mass of biomedical innovators that lead the next generation of medical discoveries to help Africa address its health and economic needs, and contribute its share to the world. The reason why Africa cannot produce its own medicines and novel products should be by choice and not because it does not have the capacity to do so.

For more information:

www.cdt-africa.org;

Tel: (+251)118 787 311

P.O. Box 9086 | Addis Ababa | Ethiopia

If you would like to contact us please email:

Dr. Abebaw Fekadu (abebaw.fekadu@aau.edu.et) or

Professor Eyasu Makonnen (eyasumakonnen@yahoo.com) or

Dr. Tsegahun Manyazewal (tsegahunm@gmail.com)

> “Ex Africa semper aliquid novi
> Out of Africa always something new
> (Pliny the Elder)”

APPENDIX: LIST OF CORE FACULTY AND ASSOCIATE MEMBERS OF CDT-AFRICA

Name	Role
Abebaw Fekadu	Head
Eyasu Makonnen	Deputy Head
Yimtubezinash Woldeamanuel	Head of Incubation Hub & Regulatory Affairs Lead
Anteneh Belete	Deputy head of Incubation Hub & Training Lead
Asrat Hailu	Research Lead
Getnet Yimer	Clinical Trials Lead
Girmay Medhin	Data Management Unit Lead
Mirutse Gidey	Natural Products Database Lead
Tsige Gebremariam	Associate faculty; Regional Bioequvalence Centre
Zaesung No	Associate faculty; Medicinal Chemistry
Charlotte Hanlon	Associate faculty; Complex Interventions coordinator
Wondwossen Gebreyes	Diaspora & OSU coordinator
Elias Said Siraj	Diaspora coordinator

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