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

ADDIS ABABA UNIVERSITY

CENTRE FOR INNOVATIVE DRUG DEVELOPMENT & THERAPEUTIC TIRALS FOR AFRICA
COLLEGE OF HEALTH SCIENCES | ADDIS ABABA UNIVERSITY | ADDIS ABABA | ETHIOPIA

REPORT FOR MEDTERM REVIEW
08 JULY 2017 – 07 JULY 2019

SEPTEMBER 14, 2019

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

IUCEA WORLD BANK GROUP

SUMMARY

Background: The Centre for Innovative Drug Development & Therapeutic Trials for Africa (CDT-Africa) was established as a World Bank supported Africa Centre of Excellence to address the serious development challenge posed by poor access to medicines (drugs, vaccines and diagnostics) in Africa through high quality training and research. The centre has been actively operational only in the past two years. This report provides details on the implementation of its plan during this time. The implementation of the plan followed three overlapping phases—preparatory, early implementation & full implementation.

Results: (1) process & organisational excellence: The first two phases, focusing on laying the foundations of CDT-Africa and expanding partnerships has completed successfully with the formation of 13 firm partnerships, establishment of the key organizational processes and infrastructures, development of guidelines and manuals that support the achievement of excellence, as well as consolidation of research platforms. Currently the centre is in full phase 3 (full implementation phase). While 40% of the funds have been disbursed, application has been made for the disbursement of 11% of additional funds, which we believe will soon be approved (Further summary in Table 1). (2) Education excellence: Two new graduate education programs that support skills development for medical discovery and development and unique for the region have been developed and approved. Overall, 323 trainees have attended or are attending our training programs. 243 trainees have attended the short courses successfully (238% of target); 21 PhD students have completed Year 1 and another 15 students are accepted for the new intake (105% of target); 54 MSc students are accepted (55.7%); two CDT-Africa faculty have obtained prestigious training fellowships; three PhD students have also received competitive internships with industry. We have initiated a post-doctoral training program, a rare opportunity in Africa, as part of our scientist development plan. Five students are in this program. We are putting in place measures to evaluate quality of education on a continuous basis. For our new MSc in Clinical Trials, the acceptability of the program by the students was encouragingly high.

(3) Research excellence: The research program in the three platforms (medical discovery & development, healthcare delivery innovation and clinical trials & regulatory affairs) is progressing satisfactorily. A natural products database has been developed; a medicinal products mapping is completed and two policy briefs are published and distributed; four topical products are being evaluated with one product close to submission for patent; one pesticide API is being developed following a needs assessment with the Ministry of Health; two phase IV vaccine development researches (one of these in ethics approval process) and four diagnostic development and evaluation projects are underway.

The Africa Bio-Hub of CDT-Africa has been recognized as a regional incubation centre by the World Bank. A mentoring and development facility, InnoCafe, has also been established to support the work of the incubation hub.

The healthcare delivery innovation projects focus on reducing maternal mortality, improving diagnosis and care of tuberculosis, scaling up care for non-communicable diseases, surgical conditions and neglected tropical diseases. Several capacity building and regulatory/ethics approval main streaming activities have been carried out. (4) Sustainability & regionality: To support the delivery on our plan and to expand the work, CDT-Africa has mobilized ~4.3 million USD. CDT-Africa has offered an opportunity for well-paying jobs for 91 staffs. This is a first taster—a successful implementation of CDT-Africa has the potential to be the foundation for a well-paying job opportunity for hundreds of thousands of Africans. CDT-Africa is also strategically attempting to be a regional centre. In the first year of the implementation of its program, 31% of its spending was on partners. This is an indication of the commitment of CDT-Africa to support regional capacity building.

Conclusion: CDT-Africa has established the key foundations and is positioned to have an impact as a regional centre of excellence. Further strategic work and ongoing institutional, national and World Bank support are needed to make CDT-Africa a true centre of excellence with regional and global impact.

Table 1 Summary of Results Achieved Against Disbursement Linked Indicators

Disbursement Linked indicators (DLIs) and results (DLRs)	**Available disbursement amount to Dec 2022**	**Achieved**
DLI #1: Institutional readiness ($1.1 million)		
1.1: Completion of Effectiveness Conditions	$600,000	$600,000
1.2: Development of the Project Implementation Plan	$500,000	$500,000
DLI #2: Excellence in education and research capacity and development impact ($4.3 million)		
2.1: Timely annual implementation of the plans	$500,000 (100,000/yr)	$200, 000
2.2: Newly enrolled students in the ACE	$1,200,000	$166,352.78
2.3: Accreditation of quality of education programs	$600,000	$75,000
2.4: Partnerships for collaboration in research & training	$200,000	$200,000
2.5: Peer-reviewed journal papers/conference papers	$300,000	$300,000
2.6: Faculty/PhD student exchanges	$500,000	$32,000
2.7: External revenue generation	$900,000	$900,000
2.8: Institution participating in benchmarking exercise	$100,000	$0
DLI#3: Timely, transparent and institutionally reviewed Financial Management ($300,000)		
3.1: Timely Withdrawal applications	$75,000 (15,000/yr)	$30, 000
3.2: Functioning audit committee	$75,000 ($15,000/yr)	$0
3.3: Functioning internal audit unit	$75,000 ($15,000/yr)	$0
3:4 Transparency of financial management	$75,000 ($15,000/yr)	$30,000
DLI#4: Timely and audited Procurement ($300,000)		
4.1: Timely procurement audit report	$150,000 (30,000/yr)	$0
4.2: Functioning audit committee	$150,000 ($30,000/yr)	$0
Total	**$6,000,000**	**$3,033,352.78 (51%)**

ACKNOWLEDGMENT

We would like to gratefully acknowledge the guidance and support given to CDT-Africa by Addis Ababa University, specifically the President and the vice presidents and their office staff. We are grateful for the day to day support CDT-Africa received from the management and staff of the College of Health Sciences. The core faculty of CDT-Africa has worked continuously and tirelessly with little incentive other than the results they see and the potential they cultivate. The hard-working full-time staff of CDT-Africa, all of them, have been instrumental in the success stories highlighted in the report. We are indebted to the Ministry of Science and Higher Education for the encouragement, responsiveness, guidance and support. We are grateful to the Ministry of Finance and the staff, without whose support none of the results would have been achieved. The Ministry of Health is also a source of encouragement and support with increasing commitment to work with CDT-Africa. The World Bank team in Ethiopia have been a constant source of support. We also would like to thank the team in the World Bank headquarters. We thank the IUCEA team for their facilitation, collegiality and guidance.

While we cannot be exhaustive in our acknowledgment, we would like to mention the contribution of the Aklilu Lemma Institute of Pathobiology. We are grateful to the Scientific Advisory Board members for their patience and commitment to offer advice and guidance on the work of the centre. The Brighton & Sussex Medical School, King's College London, the Ohio State University, especially the team of the Global One Health initiative, and Karolinska Institute, have been part of CDT-Africa from the outset and continue to make crucial contributions to the success of CDT-Africa. Our acknowledgment extends to our diaspora coordinators in the US and UK. Our colleagues at the Bio-Ventures for Global Health (BVGH) have been continuously generous and were instrumental in cultivating the vision of CDT-Africa. They remain committed friends and partners. The Sodo district and Bui city administrations and the community advisory board deserve a particular mention for their commitment to the work and for allocating spaces to CDT-Africa for field training, clinical research and pilot botanical garden.

ABBREVIATIONS AND ACRONYMS

AAU	Addis Ababa University
ACE II	Eastern and Southern Africa Higher Education Centres of Excellence
ASSET	Health system strengthening in sub-Saharan Africa
BSMS	Brighton and Sussex Medical School
BVGH	Bio-Ventures for Global Health
CDT-Africa	Centre for Innovative Drug Development and Therapeutic Trials for Africa
CHS	College of Health Sciences
CRO	Contract Research Organization
DLI	Disbursement-Linked Indicators
DLR	Disbursement-Linked Results
EACCR-2	Eastern Africa Consortium for Clinical Research
EDCTP	European and Developing Countries Clinical Trials Partnership
EFDA	Ethiopian Food, Drug and Medicines Authority
EFMHACA	Ethiopian Food, Medicine and Health Care Administration and Control Authority
EnDPoINT	Integration and scale up of care package for patients with lymphoedema in Ethiopia
EXIT-TB	Translation research into policy and practice: Scaling up Evidence Based Multiple focus Integrated Intensified TB Screening to End TB
FIND	Foundation for Innovative New Diagnostics
ICH GCP	International Council on Harmonisation Good Clinical Practice
IPK	Institute Pasteur Korea
KCL	Kings' College London
KOICA	Korea International Cooperation Agency
LMIC	Low and middle-income country
MoU	Memorandum of Understandings
NIHR	National Institute of Health Research, UK
PDO	Project Development Objective
PROFORMA	Pharmacovigilance infrastructure and post-marketing surveillance system capacity building for regional regulatory harmonization in East Africa
PV	Pharmacovigilance
SBP	Sanford Burnham Prebys
SJTU	Shanghai Jiao Tong University
SMART	Specific Measurable, Appropriate, Realistic, Time-bound
TAT-Safe	Safety of equine tetanus antitoxin for prophylactic use in Ethiopia: A phase IV multicenter study
UBC	University of British Colombia
UCSD	University of California San Diego
US$	United States Dollar

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DEVELOPMENT OBJECTIVES

The Centre for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa) is a World Bank supported Africa Centre of excellence for education and research at the College of Health Sciences, Addis Ababa University, Addis Ababa, Ethiopia. The Centre was first established as a clinical trial unit of the College of Health Sciences (Addis Ababa University) in 2014. It evolved into a regional centre of excellence in 2017 as part of the Eastern and Southern Africa Higher Education Centres of Excellence (ACE II) initiative of the World Bank with a vision of becoming **an Africa-based global institution for ground-breaking medical discoveries and development**. The project development objective (PDO) of CDT-Africa aligns with World Bank ACE II PDO of strengthening selected Eastern and Southern African higher education institutions to deliver quality post-graduate education and build collaborative research capacity in the regional priority areas. The main aim of CDT-Africa is to contribute to the sustainable development of Africa by addressing the development challenge posed by poor access to medicines through the discovery and development of novel medicines (drugs, vaccines and diagnostics), healthcare delivery innovations and assisting local production of medicines in a regional platform(Please see annex 1 for further information).

Poor access to essential medicines in Africa is not just a health concern but also has major economic and security implications (Figure 1 & Figure 2).

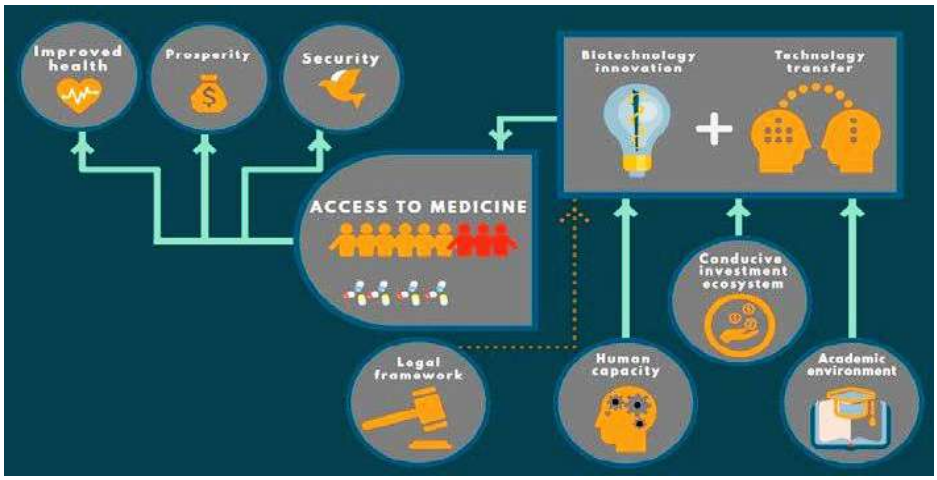

Figure 1 Path towards improved wellbeing, prosperity and peace in Africa through improving access to medicines

Nevertheless, this development challenge also presents an unparalleled opportunity to fuel Africa's growth and transformation with a prospect to bring about prosperity and security to the

continent. Moreover, African countries are now striving to initiate sustainable development of their economies by creating value additions to indigenous assets, with a potential for creating a healthy, prosperous and secure Africa that can contribute its share for the wellbeing of the globe. Ensuring this happens requires producing the requisite skilled manpower as well as vision and strategic thinking. Creating conducive investment ecosystem, and changing the academic environment to focus on technology transfer and biotechnology innovations are also important. Effectiveness of these consolidated efforts would foster access to medicines in Africa, which, in turn, cultivates the health, prosperity, and security of the continent (Figure 2). CDT-Africa works to achieve these or work with partners that lead the achievement of these objectives.

Figure 2 Potential contribution of CDT-Africa to the achievement of the Sustainable Development Goals in Africa

With a long-term ambition of finding sustainable therapeutic solutions in Africa, CDT-Africa has developed its 20 Years (2017 – 2036) strategic direction divided logically into four five-year segments or periods:

Table 2 Strategic direction of CDT-Africa with 5-year themes and segments

1st 5 years: Innovation led	2nd 5 years: Discovery led
Strengthening foundation	Consolidation and expansion (Discovery led)
Strategic capacity expansion	National excellence
Education excellence	Regional recognition
Innovation	Strategic capacity expansion
Clinical trials (Phase I to IV)	Regional excellence (Research + education)
3rd 5 years: Invention led	**4th 5 years: Impact led**
Sustainability on solid ground	Leading-edge
Strategic capacity expansion	Global recognition & excellence
Invention	Preferred by LMIC students
Research excellence	Attract students of developed country
Education excellence	Preferred CRO
Clinical Trials network	Preferred by Industry
Regional excellence	Multiple centres established
Public engagement	Self-sustaining
	Regional Clinical Trials Network

The first five-year segment, covering the years 2017 – 2021/2022, is supported by the World Bank to put in place all the key foundations of a sustainable African program. In the period 15 June 2016 – 31 December 2022, the World Bank has allocated a funding amount of US$ 6 million, through the IDA provision, for implementation of the project, which is contingent on satisfactory achievement of agreed Disbursement-Linked Indicators (DLIs). There are five PDO level DLIs, with each associated with Disbursement-Linked Results (DLRs) and unit disbursements rates.

The Centre has also developed a five years strategic plan structured with seven strategic themes to meet the DLRs and indicators of the project:

Table 3 The 7 goals of CDT-Africa linked to its development objectives

Theme	1: Institutional excellence	2: Education excellence
Goals	Establish CDT-Africa Consortium Foster collaborations Grow as a regional centre of excellence	Provide professional development opportunities Support knowledge exchanges
Theme	3: Research excellence	4: Quality excellence
Goals	Function as leading global study site Strengthen biomedical ventures and commercialization Strengthen medicine regulatory system	Implement quality assurance of research and education Obtain public buy-in and accountability
Theme	5: Sustainability	6: Best financial practices
Goals	Obtain sustainable funding mechanisms Institutional advancement plan and implementation Infrastructure	Establish transparent financial system that meets international best practices
Theme	7: Best procurement practices	
Goals	Place best procurement practices	

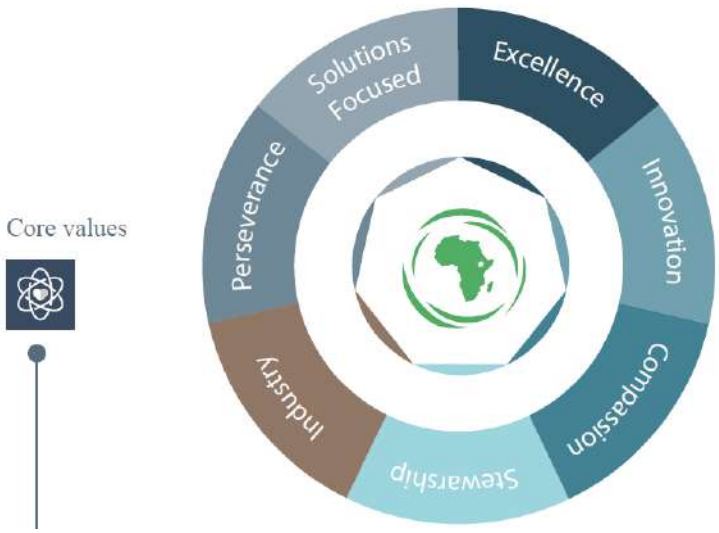

Figure 3 The core values of CDT-Africa

CDT-Africa is driven by the core values in Figure 3. We work to achieve **excellence** in all things we do. We believe **innovation** is at the heart of the transformation of institutions and nations. Our dealing with partners, students, people, the environment and animals is guided by **compassion**, respect and ethics. We treat what is given to us with due diligence and **stewardship**.

Achieving our objectives requires working hard with patience and hopefulness-thus **industry** and **perseverance** are key foundations for CDT-Africa. While problems abound, we choose to be **Solutions-focused.**

In this mid-term report, we describe the activities and progress made in implementing the plans of CDT-Africa since its establishment just over two years ago. The report is organised around the results relevant to the disbursement linked indicators—institutional readiness, education excellence, research excellence and finance and procurement management. As per the guidance given for this report, relevance of design, fiduciary matters, and issues of restructuring are discussed in the end.

PROGRESS OF IMPLEMENTATION

CDT-Africa has taken a "Phased Implementation" approach to deliver on its program (Figure 4). These phases were naturally overlapping. Phase I (Preparatory) focuses on setting up all the

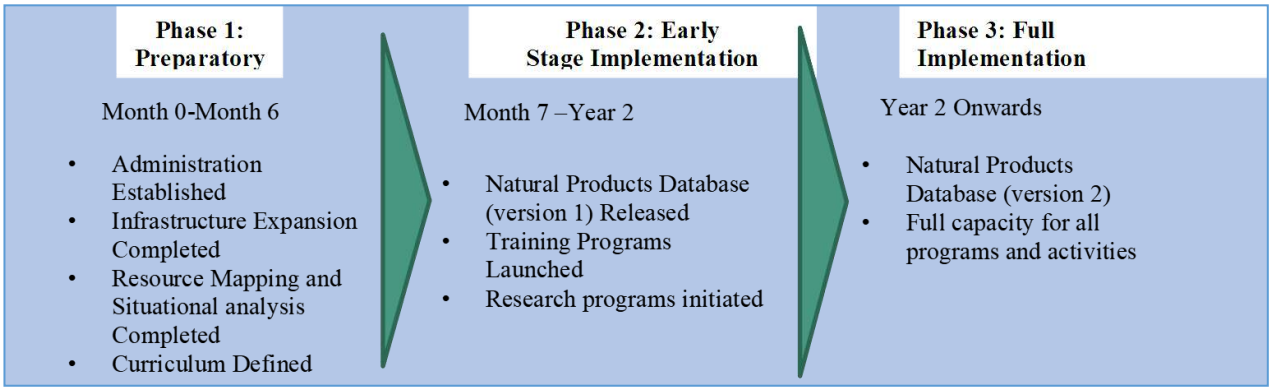

Figure 4 The 3 phases of implementation

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 to agree with stakeholders the objectives and strategies of the Centre. Phase II (Early implementation), aimed that all curricula are completed; database for natural products compiled and research begun; trainings begun; and program plan revised based on findings. Phase III (Full implementation), targeted that all activities of the Centre take place in full capacity; and internal and external monitoring and evaluation systems shaped the performance of the Centre.

Active work of the Centre has been since July 2017, and the last two years were promising for meeting development objectives of the Centre. As a regional platform, CDT-Africa supported capacity building across eastern and southern Africa. Phase 1 and Phase 2 have been virtually completed. We have embarked on the full implementation of the program as in Phase 3.

RESULTS FRAMEWORK: KEY INDICATORS AND ACHIEVEMENTS

Details on DLIs and allocated amount of funds for the entire project period are described in the following sections.

1. DLI #1: INSTITUTIONAL READINESS

Table 4 Results linked to institutional readiness

DLI #1: Institutional readiness ($1.1 million)		
1.1.	Completion of Effectiveness Conditions	$600,000
1.2.	Development of the Project Implementation Plan	$500,000
	Total	$1,000,000
	Achieved	$1,000,000 (100%)

Fulfilling all the conditions for effectiveness under DLI #1, CDT-Africa was disbursed with US$ 1,000,000: US$ 600,000 for completion of effectiveness conditions (DLR#1.1) and US$ 500,000 for effective development of the project implementation plan (DLR#1.2). The centre has been using this for establishing the Centre and taking steps in education and research works.

1.1. Project launch

The Centre held its first Consortium meeting on 23 October 2017 (Figure 5). The meeting fostered scientific learning and strengthened partnership.

Figure 5 CDT-Africa 1st consortium meeting, 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 5).

Table 5 Partner participation in the 1st CDT-Africa consortium meeting, 23/10/2017, Addis Ababa, Ethiopia

Sector	Institutions*
Ministries	Ministry of Health, Ministry of Education, Ministry of Science and Technology
National Universities	Mekele University, Bahir Dar University, Debre Tabor University, 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

A follow-up meeting was conducted a year after and partners evaluated the Centre's report and given inputs (Figure 6).

Figure 6 CDT-Africa Second Consortium meeting, July 2019, Addis Ababa, Ethiopia

1.2. Infrastructure

1.2.1. Office space

With modest investment, the Centre established and setup its office (Figure 7) within the College of Health Sciences, Addis Ababa University, 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 7 CDT-Africa main office

Discussing with the Vice-President's Office of the AAU, the Centre secured dormitories for its regional PhD students.

1.2.2. CDT-Africa Biomedical Incubation Hub

CDT-Africa is establishing its biomedical incubation hub (Africa Bio-Hub) in a reasonably large G+1 building (Figure 8) that Addis Ababa University granted at sefereselam campus. The Centre is under renovation and refurbishment, and procurement of laboratory equipment is in progress. The hub will enhance technology transfer from academia to industry and create a milieu that encourages investment. The work of the hub will include: i) technology innovation, ii) business development, iii) analytical technology support, iv) biomedical product supply, and v) education and training. Head and Deputy Head, both having academic rank of Associate Professor, lead activities of the Hub.

Figure 8 CDT-Africa's Africa Bio-Hub

At the initial stages, technology innovation of the Bio-Hub shall focus on process development and natural product discovery. Subsequent work will extend the task to include novel biomedical products, such as novel anti-microbial drugs, vaccines and diagnostics. Client (industry)-based training sessions, high-technology service, and biomedical product support will be developed

into a dual tool both for the Hub's self-sustainability and for industry R&D activation. For education and training program, essential responsibility of an incubation hub, the Bio-Hub will*-develop a unique public curricula and manage them to fulfil the needs from the perspective of the continent of Africa. A successful implementation of plans will lead to major boost in the health, productivity and security of Africa.

1.2.3. CDT-Africa Innovation Café (InnoCafe)

CDT-Africa has almost completed renovation of InnoCafe space with a beautiful view at the top floor of the administrative building of the College of Health Sciences, Addis Ababa University, for use as InnoCafé (Figure 9). The innoCafe has space to sit up to 20 innovators at any one time with additional mentoring and meeting spaces. The InnoCafe will be used as a comfortable space for innovators to develop and test their innovations, be mentored, meet with businesses and be supported to refine and sale their products. The InnoCafe will also be a space for peer development of ideas. Innovators are expected to come from across Africa. Currently four candidates to work in the InnoCafe are identified and will start work as soon as the renovation work is completed. We also aim to invite at least two innovators from African countries other than Ethiopia taking advantage of the platform to be created by the Africa Innovation Week (October 28-November 2, 2019).

Figure 9 CDT-Africa Innocafe at final stages of renovation

1.2.4. CDT-Africa Clinical trial Unit

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 Centre visiting clinical trials, 27 February 2018, University of Gondar, Gondar, Ethiopia.

The Centre conducted modest renovation (Figure 11) and procured equipment and supplies to advance capacity of the Unit to meet optimum standard. The Unit is officially launched by the Chief Executive Director of the College of Health Sciences, Addis Ababa University.

Figure 11 CDT-Africa Clinical Trial Unit completed renovation and official launched by CHS CED

1.2.5. CDT-Africa field study site

In addition to existing clinical study sites, CDT-Africa has obtained two field study sites in Sodo, the Gurage zone. Sodo is one of the study sites of CDT-Africa—one health delivery innovation study and one clinical trial are being conducted. The district is also endemic to cutaneous leishmaniasis, one of the target conditions for CDT-Africa. One of the sites (a 2000 Sqm field) will be used to establish a clinical trials and field laboratory facility. The second site (a 3000 sqm field) is to be used for growing medicinal plants from the region. The facilities will also be used to encourage innovation in the region, particularly by engaging high school students and their teachers.

Figure 12 Field clinical study site and pilot botanical garden site for medicinal plants

[Dr Wondwossen Amogne, Director of Research & Technology Transfer, W/ro Asegedech Abate, Managing Director of the College of Health Sciences and Ato Feleke Asfaw, Chief Administrator of the Sodo district, Ato Zemecha Endale, Chief Administrator of the Bui City Administration

and members of the Community Advisory Board and CDT-Africa were in attendance during the hand over of the study sites to the centre.]

1.3. Human resource

The Centre has employed key qualified staff and expanded committed partnership support 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 (Figure 13). Started with eight core-faculty, the Centre now has over 100 contributors: Faculty, associate faculty, full-time staff, and contract staff. The employees of the Centre have been in duty since 12 June 2017.

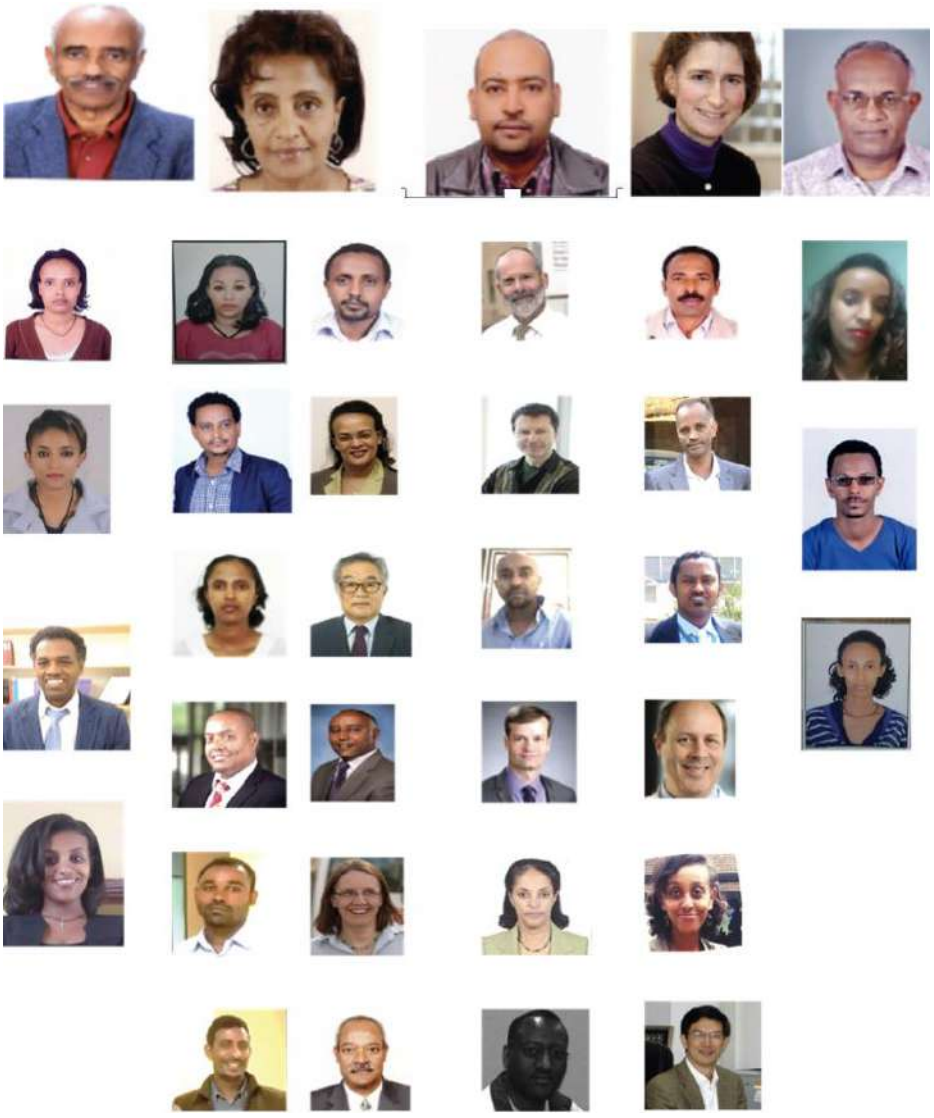

Figure 13 Some of CDT-Africa faculty and staff

Overall, CDT-Africa has employed 91 full time new staff with relatively good wages. The centre used a principle of "living wage" to ensure that a basic salary standard was offered to all its staff.

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.

1.4. Operation systems

In the reporting period, the Centre has developed operation systems and modalities to maximize effectiveness;

- The Center developed its 5 years strategic plan, which is being revised currently owing to the rapid expansion of objectives, responsibilities and tasks.
- Office Manuals were approved by AAU and the World Bank
- SMART planning process was followed for annual work plan and developing Guidelines
- System, strategies and guidelines of human resource, communications and branding, staff development, documentations and recording developed and are in use
- Focus on excellence: one of the key explorations of the centre was on how to ensure all operations support the achievement of excellence by the centre.

2. DLI#2: EDUCATION EXCELLENCE

Table 6 Key results in education and research capacity and disbursement status

DLI #2: Excellence in education and research capacity and development impact ($4.3 million)	Disbursement amount until Dec 2022	Achieved until July 2019
2.1: Timely annual implementation of the plans	$500,000 (100,000/yr)	$200, 000
2.2: Newly enrolled students in the ACE	$1,200,000	$166,352.78
2.3: Accreditation of quality of education programs	$600,000	$75,000
2.4: Partnerships for collaboration in research & training	$200,000	$200,000
2.5: Peer-reviewed journal papers/conference papers	$300,000	$300,000
2.6: Faculty/PhD student exchanges	$500,000	$32,000
2.7: External revenue generation	$900,000	$900,000
2.8: Institution participating in benchmarking exercise	$100,000	$0
Total	$4,300,000	$1,673,352.78 (38.9%)*

*For some of the results, we are awaiting verification and decision on disbursement

2.1. Timely annual implementation of the plans

Though active implementation of the project was started on July 2017, overall progress of implementation of the plans has been satisfactory. Disbursement request was submitted to World Bank for effective implementation of the plans in the years 2017 and 2018. Please note that, focusing on sustainability and innovation, CDT-Africa has developed new projects and programs that were not part of the initial implementation plan. The implementation of these new project-specific plans are being monitored by third parties. However, all the projects were developed in line with the objectives of CDT-Africa. No projects were supported that were not relevant to achieving the goals of the centre.

2.2. Newly enrolled students in the ACE

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.

2.2.1. Postdoctoral program

Postdoctoral program is a neglected critical element for Africa's development. African PhD graduates lack postdoc trainings to advance their research skills; instead, they recruited into

teaching and administrative work, with little or no time to do research or utilize the skills acquired in PhD training. Very few African universities offer postdoctoral training, while African PhD graduates seek postdoctoral training abroad, where the training earned may not be useful to the host country. It also leads to 'brain drain'. CDT-Africa believes that Africa needs to build capacity for Postdoctoral programs to transform universities into research hubs, promote research excellence and leadership, produce skilled staff to mentor the next generation of well-trained scientists, and boost knowledge-based African economy.

CDT-Africa has five postdoctoral fellows engaged in drug development (2), diagnostic development (1), vaccine development (1) and complex intervention (1) works. With the program, the Centre is empowering young PhD graduates to acquire additional skills and experience in medical discovery and developments. The program gives the postdoctoral students a dedicated time for focusing on a research project, access to modern facilities and mentorship from senior scientists/researchers, critical skills and confidence to be independent research leader, financial support, opportunity for collaboration/partnership, opportunity for publications, and opportunity to define their career path.

2.2.2. PhD programs

Table 7 PhD students

21 PhD students: 08 July 2017 – 07 July 2019						
Program		Total	National (N)	Regional (R)	Female N	Female R
PhD	Target	33	26	7	12	4
	Achieved	21, 64%	18, 69%	2, 29%	5, 42%	2, 50%

Table 8 PhD students by gender, region and disbursement status

Gender	Region	Reported	Eligible	Responded	Verified	$/unit	Disbursed
Female	National	3	3	3/100%	0, 0%	-	-
Male	National	19	17	17/100%	0, 0%	-	-
Female	Regional	2	2	2/100%	2, 100%	60,000	60,000

2/21 students disbursed through 2017/18; $60,000/$543,000 targeted until Dec 2022 (11%) [NB: No application made for the five postdoctoral students]

Until 07 July 2019, the Centre enrolled a total of 21 PhD students, and additional 13 PhD students are just recruited for enrolment in the 2019-20 academic year. The Centre plans to meet the overall PhD target in 2020, ahead of time.

The Centre has also developed a new PhD program in Translational Medicine in three tracks (vaccine development, drug development and diagnostic development) 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 14).

Figure 14 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 needs assessment survey (Table 9) 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, 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 9 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 15).

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

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, submitted a revised version of the curriculum for the office, and approved, followed by approval at AAU Senate. The Centre received 70 applications for enrolment in 2019-20 academic program.

2.2.3. New MSc program

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 Centre 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 confirmed high need for the program to improve access to interventions in Africa and accelerate regional development.

Table 10 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	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 Centre 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 Centre advertised the new MSc in clinical trials and received over 500 applications in 2018 and over 650 in 2019 academic years from all over Africa.

Table 11 Achievement status of MSc compared with target

54 students: 26* - 2018/19; 28 new - 2019/20: 08 July 2018 – 07 July 2019						
Program		Total	National (N)	Regional (R)	Female N	Female R
MSc Clinical trials	Target	97	78	19	40	9
	Achieved	54, 56%	39, 50%	15, 79%	20, 50%	13, 144%

*Of the total 26 eligible MSc students, 21 (81%) were verified by IUCEA and the Centre disbursed

Table 12 MSc students and disbursement status by gender and region

21/26 student disbursed through 2017/18; 68,500/309,500 until Dec 2022 (22%)							
Gender	Region	Reported	Eligible	Responded	Verified	$/unit	Disbursed
Female	National	10	10	10/100%	6, 60%	3,000	18,000
Male	National	11	11	10/100%	10, 91%	2,500	25,000
Female	Regional	3	3	10/100%	3, 100%	5,000	16,500
Male	Regional	2	2	10/100%	2, 100%	4,500	9,000

2.2.4. Short-term courses

Table 13 Short term course results by target

Technical result: 243 participants of 102 targeted until December 2022 (238%)						
Program		Total	National (N)	Regional (R)	Female N	Female R
Training	Target	102	81	21	51	16
	Achieved	243, 238%	204, 252%	39, 186%	66, 129%	17, 101%

Until July 2019, the Centre provided training for 243 participants across Africa with the aim to maximize skills and critical thinking in research and therapeutic developments in its partner institutions. However, of the total 243 trained, only 76 (31%) were verified by IUCEA and the Centre disbursed:

Table 14 Short courses by region, gender and disbursement status

Financial result: 76/243 disbursed through 2017-19; $38,000							
Gender	Region	Reported	Eligible	Responded	Verified	$/unit	Disbursed,14%
Female	National	33	28	27/96%	19, 70%	5000	6,597
Male	National	116	87	74/85%	43, 58%	400	11,944
Female	Regional	13	9	6/67%	4, 67%	1000	2,778
Male	Regional	17	12	9/75%	6, 67%	800	3,333

The Centre organized the first training, Medicines Development and Regulation, March 2018, and trained 26 participants. The training enabled participants (Figure 12) 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 16 Participants of "Medicines Development and Regulation" training held in March 2018, Addis Ababa, Ethiopia

The Centre provided the second training, Good Clinical Practice and Health Research Ethics, in April 2018, and trained 41 participants. The training equipped participants (Figure 13) 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 17 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 in June 2018, and trained 23 participants. The training informed participants (Figure 14) 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 (zoonosis, safety and efficiency data).


Figure 18 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, again in June 2018, and trained 41 participants. The training provided participants (Figure 15) 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 19 Participants of "Molecular Epidemiology, Diagnostics and Genetic Engineering" training held on 18 - 22 June 2018, Addis Ababa, Ethiopia.

Subsequent trainings have included, among others, approaches to personalised medicine with foucs on genomics; genomics analysis; systematic reviews; and grant writing.

2.3.Quality of education programs

Table 15 Accreditation

Achievements for accreditation			
Name of academic program	Accreditation body	Achieved	Total funding
MSc in Clinical Trials	National	$75,000	
PhD in Translational Medicine	University senate approved (Submission for national level approval)	--	
Total	$75,000 (Application submitted for verification)		$600,000

The Centre has 2 new graduate programs: MSc in Clinical Trials and PhD in Translational Medicine. These programs have been approved by a series of a relevant national bodies, including

the university senate. The MSc program has also obtained a national level accreditation from the Ministry of Science and Higher Education and has completed the national accreditation path. We have thus applied for disbursement of $75,000 for the MSc program. We are awaiting for the final approval for the PhD before applying for disbursement.

Quality of the delivery of the MSc program was assessed through continuous evaluation of each teaching module. Overall, over 90% of the ratings are either excellent or acceptable (average), with over 99% of respondents indicating that they would recommend the program to others. The figure below is derived from a total of 195 responses collected from the MSc students at the end of each course module

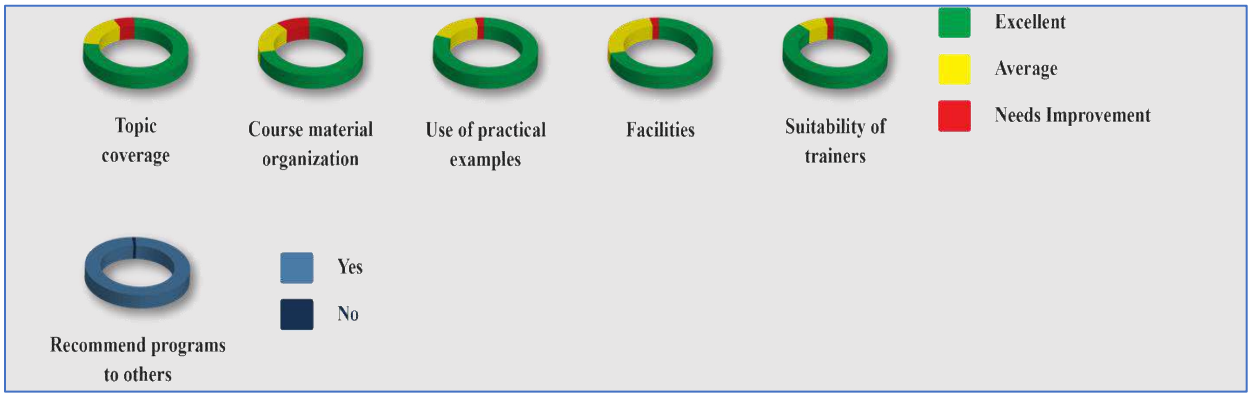

Figure 20 acceptability of the training program by students

2.4.Partnerships for collaboration in research & training

CDT-Africa has made a deliberate effort to expand its partnerships from the outset. Extensive partnerships within Ethiopia, eastern and southern Africa, Asia, Europe and North America have contributed to the success of the centre, with clear value additions (Table 17). Further work to strengthen these partnerships continues.

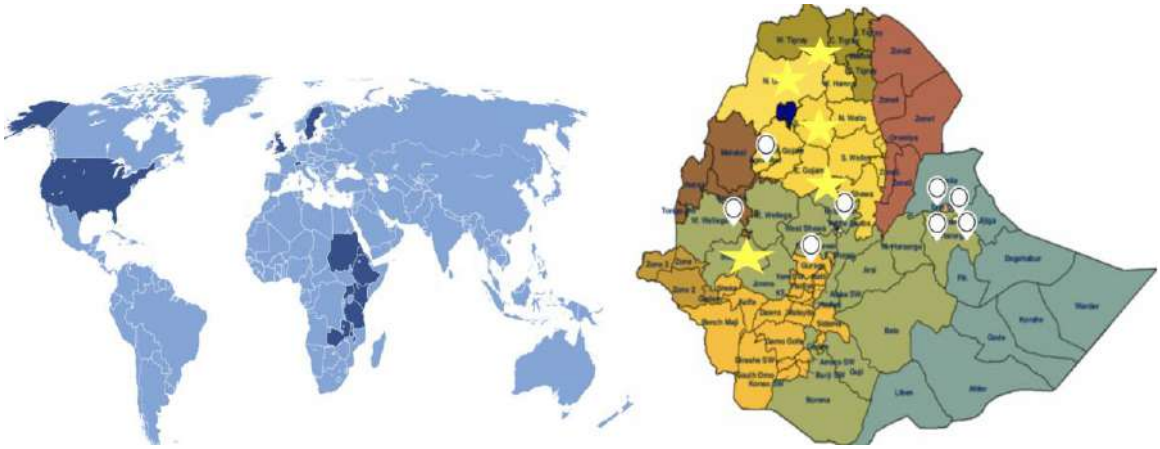

Figure 21 World map showing countries where partner institutions or students come from. Map of Ethiopia shows regions where partner institutions (indicated by yellow stars) and project sites are found-

Table 16 Value chain enhancement through partnership

Quality Education →	Quality Research →	Quality impact
Short courses	Drug Discovery → Clinical Trials	Dissemination
MSc/PhD Training	Database → Preclinical	Ownership
Postdoctoral/Fellowship	Studies → Translational studies	Access
Training		Growth

Table 17 MoU accompanied by signed proposals that outlines at least a two-year collaboration and partnership work- program

Main partner	Type of partner
Uganda Virus Research Institute	Public
King's College London (UK), University of Cape Town (South Africa)	Public
Brighton and Sussex Medical School (UK)	Public
National Institute for Medical Research, MUHIMBILI Center (Tanzania)	Public
Karolinka Institute (Sweden)	Public
ViNS Bioproducts Limited (India)	Private
Total funding amount	$200,000
Achieved	$200,000 (100%)

CDT-Africa established partnership with national, regional and international institutions (Figure 16), including University of California San Diego (UCSD), Sanfor Bernham Prebys Drug Discovery Institute, Emory University, Foundation for Innovative New Diagnostics (FIND), African Network for Diagnostic Innovation (ANDI). Progressive meetings were held with Ethiopian Federal Ministry of Health and the Ethiopian Ministry of Industry for potential collaborations (Both meetings chaired by the State Ministers). The Centre has signed Memorandum of Understanding with 13 institutions, of which six are accompanied by signed proposals that outline at least a two-year collaboration and partnership work program.

Figure 22 CDT-Africa partner institutions

At its initial stage, the Centre visited its five national partner universities (Figure 17) and signed Memorandum of Understanding for collaboration on education and research. In general, the Centre established strong partnerships with potential institutions, while more work is needed to fully engage its African partners.

Figure 23 CDT-Africa initial on-site visits and discussions at Debre Markos and Debre Tabor Universities

The Centre signed cooperation agreements with the Shanghai Jiao Tong University (Figure 18). The agreement specifically focuses on student and faculty exchanges, conducting joint research and teaching, and developing an Africa pharmacopeia and development of guidelines and application of use of traditional medicine. One exchange visit of 11 students and faculty has been hosted already by CDT-Africa and a team from CDT-Africa is scheduled to visit Shanghai on exchange. A second team is also scheduled to visit CDT-Africa at the beginning of next year. An

initial work on the Africa Pharmacopeia has characterised two medicinal plants and five more plants are targeted for the next exchange meetings.

Figure 24 AAU - CDT-Africa and Shanghai Jiao Tong University (China) signing cooperative agreement

CDT-Africa has also developed a promising relationship with the University of British Colombia (UBC), Canada. The discussion held between CDT-Africa and the visiting UBC team on major collaboration areas, including analytical capacity, skills support, instrumentation and potential for genome wide screening to support personalised medicine develpment. Moreover, infrastructure capacity building, networking, teaching and clinical trials were the other major collaboration areas discussed on the event (Figure 19). The UBC team held productive discussions with the President of Addis Ababa University, the Vice President for Research & Technology Transfer and the Vice President for Institutional Development. Subsequent joint training for two weeks with a leading scientist, Prof Corey Nislow, supported by an Ethiopian diaspora, Jamal Kurtu.

Figure 25 CDT-Africa and University of British Colombia (Canada) delegates at AAU

CDT-Africa greed with Institute Pasteur Korea (IPK) and BioSquare Inc., South Korea to further strengthen collaboration on research focusing primarily on diagnostics technologies and clinical studies for leishmaniosis, dengue, malarial and other neglected tropical diseases (Figure 20). The South Korea team visited Addis and a Memorandum of Understanding was signed between the two for collaboration. The agreement included exchange of postdoctoral and graduate students for study, research or learning opportunities; by faculty or staff for research, teaching, technology transfer and sharing opportunities; joint venture and commercialization of products; and organizing joint workshops, seminars, or other mutually beneficial activities. The Biosquare and CDT-Africa have obtained a small grant that supports a postdoc and establishment of a Biobank at CDT-Africa focusing on leishmaniasis.

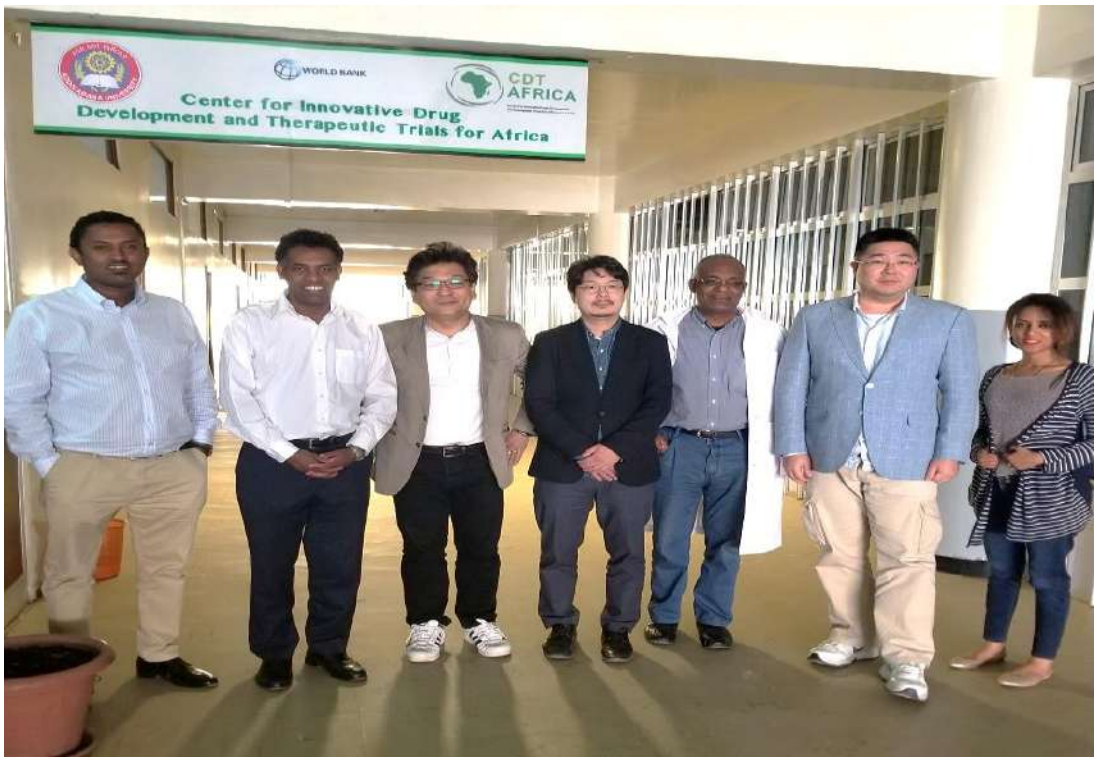

Figure 26 Institute Pasteur Korea (IPK) and BioSquare Inc., South Korea, delegates visiting CDT-Africa

The president of AAU also signed MoU with Kings College London, the University of Sussex, and the University of Brighton (Figure 21). The agreements were signed to deliver scholarly interaction, cultural interchange, co-operative research and other forms of academic collaboration including co-development of curriculum, students and staff exchanges with particular focus on supporting CDT-Africa and the possibility of establishing a joint (tripartite) global centre. These partner institutions are internationally recognized for their work in the area of health and natural sciences, philosophy, policy and political sciences. Both Brighton and Sussex Medical School, represented by the University of Sussex and University of Brighton, and King's College London have been outstanding partners from the time of the conception of CDT-Africa.

Figure 27 MOU signing between Addis Ababa University, University of Sussex and University of Brighton and King's College London.

[The president of AAU, Prof Tassew Woldehanna, and Prof Funmi Olonisakin, Vice-President and Vice-Principal International at King's College London signing a tripartite agreement (MOU) between Addis Ababa University, King's College London, University of Brighton and University of Sussex, in the presence of Prof Martin Prince, Director of King's Global Health Institute and Dr Abebaw Fekadu, Head of CDT-Africa,]

The Centre had on-site visits from private companies, including Novartis Company (USA) (Figure 22), ViNS Bioproducts Limited (India), Kilitch Drugs Ltd (India), and Estro Import and Export PLC (Ethiopia), for collaboration and joint venture for medical discovery and development.

Figure 28 Novartis Company team visiting CDT-Africa (at the Phase I Clinical Laboratory room)

2.5.Peer-reviewed journal papers/conference papers

Table 18 Articles published by CDT-Africa in peer-reviewed, PubMed-indexed journals

Year	No. published	Max funding amount	Verified and disbursed
2017-19	113	$300,000	$1,030,000 verified, the max. $300,000 disbursed

The Centre is already disbursed $300,000, which is 100% of the funding amount for the DLR. Eligible amount was $1,030,000 but the max. $300,000 disbursed. The Centre published 53 and 60 peer-reviewed, PubMed indexed articles in 2017-18 & 2018-19, respectively. Authors affiliated from national, regional, and international partners were included in the articles.

2.6.Faculty/PhD student exchanges

This DLR aims to support faculty/PhD student exchanges to promote regional research and teaching collaborations, and $500,000 is allocated for the task, to be used until 31 December 2022. CDT-Africa hosted 11 international students and faculty for exchange from Shanghai Jiao Tong University from China. This three week exchange visit aimed at conducting joint research on

traditional medicine and drafting protocol for Africa pharmacopoeia. Protocol for pharmacopeia was developed and an initial pharmacopeia work was completed for two traditional medicinal plants.

However, only four of the 11 exchange students and faculty were verified with just $32,000 of the expected $88,000 disbursed to CDT-Africa. We think this may have been due to language barrier. During their visit, there were 3 dedicated translators for the group.

Figure 29 students and faculty from SJTU, China, for a 20-day exchange visit at CDT-Africa

The Centre has couple of student and faculty exchanges to include in the next reporting period.

2.7.External revenue generation

Table 19 Externally generated funds and disbursement status

Externally generated revenue, max $900,000 verified and disbursed (100%), Source of funds	Budget amount
National Institute for Health Research Project 1	$1,479,689.9
National Institute for Health Research Project 2	$1,046,567.6
EDCTP Project 1	$1,026,000
EDCTP Project 2	$171,000
EDCTP Project 3	$250,190
EDCTP Project 4 (and 5)	$205,200
ViNS Bioproducts Limited	$50,000
Total achieved	$4,228,647.5 (940%)
Max. fund allocated	$900,000
Disbursed	$900,000 (100%)

The Centre has secured seven new grants in the past two years to be implemented over the coming 4-5 years, with a total generated grant coming to CDT-Africa of over $4 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 19), while implementation of the projects has started since January 2018.

Figure 30 CDT-Africa projects launch ceremony 20 June 2018, Addis Ababa, Ethiopia

2.8.Institution participating in benchmarking exercise

CDT-Africa has not yet achieved this DLR. Implementation of this DLR requires full engagement of the AAU leadership than the role needed from CDT-Africa. However, CDT-Africa needs to own it and push the exercise forward, and the Centre will do this and come up with a significant achievement in the 2019 - 20 physical year.

3. DLI#2: RESEARCH EXCELLENCE

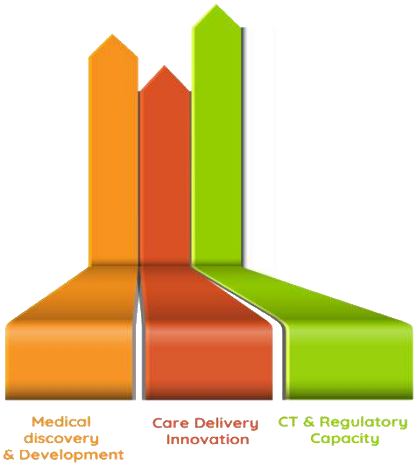

Figure 31 The three research excellence platforms of CDT-Africa

The three main platforms relevant to medical product development and application in which CDT-Africa is working on are: medical discovery & development, healthcare delivery innovation and regulatory capacity.

Product development, with parallel capacity development, is in progress for drugs, vaccines and diagnostics. These product development activities have focused on developing a natural products database, mapping herbal products, skin products development, improving quality of diagnostic tests and introducing/adapting new tests as well as safety (pharmacovigilance) studies of vaccines. The healthcare delivery innovation 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 neglected tropical diseases, non-communicable diseases, mental and substance use problems, surgical and dental care, and maternal healthcare in Ethiopia. In terms of regulatory capacity, the work has involved capacity building through applied training for ethics and regulatory practitioners, strengthening a Phase 1 clinical trial centre, engagement of relevant stakeholders and mainstreaming ethics approval for clinical trials. The centre's research engagement also included dissemination through publication and research presentations.

3.1.Drug development

3.1.1. Natural products database:

As an initial pilot, a database of 200 plants with evidence of pre-clinical safety and efficacy has been developed. This database is to be expanded.

3.1.2. Biobank:

Securing a biobank that will support drug discovery as well as diagnostic discovery.

3.1.3. In-house development of antiseptics:

The aim is to develop a marketable novel antiseptic for use by health care facilities-while the healthcare facilities are prioritised, the product has the potential to serve the public need.

Phase I is completed, and further development of the product is in progress.

Figure 32 An antiseptic product under development

3.1.4. Endemic plant extracts for limb care

The aim is to identify effective and safe endemic plant extracts against infection, inflammation, pain and with wound healing properties.

Phase I (Identification Stage) is completed. 46 potential plants available locally were identified. A short list of 10 plants was then developed based on prioritisation criteria informed by the World Health Organization (Efficacy, safety profile, edibility, abudance, plant parts, accessibility, endogenous knowledge). 10 plants have been collected at the end of the identification phase. Phase II (Pre-clinical discovery stage) is in progress to evaluate pharmacological activity of extracts. To support this, wound swabs have been collected from 100 patients with skin infection.

3.1.5. Phase IV studies on mass praziquantel administration for schistosomiasis

The aim is assess safety and efficacy of single dose praziquantel in eliminating schistosomiasis among elementary school children in Southern part of Ethiopia. The study is supported by EDCTP2, has been completed and data are being analysed.

3.1.6. Optimization of praziquantel therapy for S. mansoni in preschool-aged children

The aim is to assess curative rate of 40 mg/kg single dose praziquantel in *S. mansoni* infection and safety. Fund has already been secured from EDCTP and the study will be launched at the end of September, 2019.

3.1.7. In-country development of an insecticide against mosquitos.

The aim is to develop procedure for bench scale production of this particular pesticide. This project is being launched following a needs assessment work. Protocol developed with 12 alternative procedures. Anticipated results in the coming 6 months barring any delays in obtaining key reagents.

3.1.8. Medicinal products mapping

As part of a resources mapping and needs assessment exercise, we conducted a medicinal products mapping research in which we evaluated resources available for meeting the medicinal products need and the gaps. In this study, we evaluated the availability of essential resources, such as skilled man power, pharmaceutical manufacturing plants and their R & D capacity, clinical trials resources, vaccine and diagnostics products production and manufacturing capacity, etc. The study was conducted in 9 Eastern and Southern African countries hosting a quarter of the population of Africa (n=340 million). The countries were selected primarily on the basis of the CDT-Africa partnership and proximity to Ethiopia. 69 companies producing drugs were identified with nearly half from Kenya. None of the manufacturing industries have meaningful R&D capacity and none of these industries produced WHO prequalififed products. While there is emphasis on importing API for supposed cost efficiency reasons, there is a huge unmet need for access to essential medicines—up to 80% of primary care facilities lacking essential medicines at any given time. The vaccine and diagnostic manufacturing capacity were much more neglected—perhaps vaccine due to external donation and support. The sustainability of this reliance on external support seems unsustainable. The main challenge identified for local production of medicines (drugs, vaccines or diagnostics) is to do primarily with the lack of access to skilled manpower. The mapping exercise demonstrated a clear need for building local expertise as an immediate priority. Two policy briefs were produced from this study (Figure 33) and distributed widely.

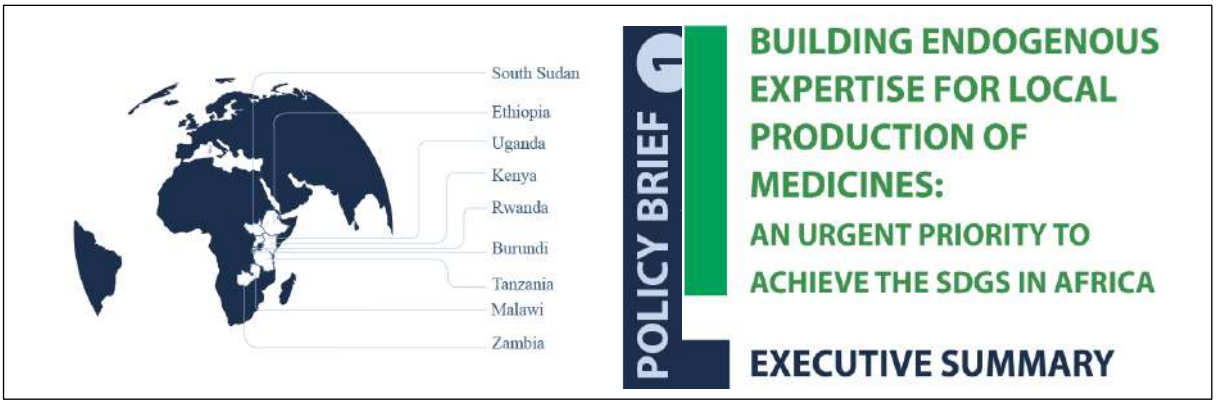

Figure 33 Study countries and policy brief

3.1.9. Africa Pharmacopeia

As indicated previously, the study aims to develop a physical and limited chemical description of medicinal plants in Africa, starting from Ethiopia and the east African region. This is a partnership work with the Shanghai Jiao Tong University (SJTU). Prelimninary description of two plants has been made and a further three will be described in January 2019.The plan is then to accelerate after the pilot procedures are established.

3.1.10. Other relevant activities

- Organised two celebrations of the International Clinical Trials Day with participation of national, regional and international partners.
- Organised one research day at the College of Health Sciences.
- Participated in a 5-day exhibition during the Research week of the Addis Ababa University. During this exhibition, demonstrations of devices and video clip presentations of the objectives and activities of CDT-Africa was one of the attractions of the event.
- Strengthening the clinical trial capacity was one of the priorities.
    - In support of this, we have established relationship with Blue cloud, with opportunities for online clinical trials ethics training for staff of CDT-Africa.
    - The data management unit has been strengthened with employment of a data manager and strengthening the data management system. This includes the use of electronic data capture using free software (ODK) and trainings to enable compliance to standards of data protection. Six trial nurses have been employed.

- Steps to expedite clinical trial ethics approval are being coordinated by CDT-Africa (e.g., establishment of a national clinical trials advisory council to help streamline clinical trials approval process).
- Two funding applications have been submitted for two relatively large cluster randomised clinical trials. One of the studies includes explicit capacity building inputs for the clinical trials programme.
- One clinical trial (behavioural) is in progress with a Post-doctoral and a PhD student linked to it.
- We are in discussion with the Federal Ministry of Health to carry out a clinical trial for cutaneous leishmaniasis.
- We are in preliminary discussions with the FDA for further collaboration on Phase 1 trials.

3.2.Diagnostic development

3.2.1. Diagnostic development for leishmaniasis

The aim is to develop a point of care diagnostic tool for leishmaniasis. The project has a small grant supported by Korea International Cooperation Agency (KOICA), and is implemented in partnership with Institute Pastor Korea (IPK) & Biosquare Ltd (South Korea). One Postdoctoral fellow will travel to IPK/Biosquare for acquiring bench-level skills; scheduled in October. Establishing a biobank is part of the project. Further aim is that, if the work is successful, a small production facility will be established within CDT-Africa to supply endemic regions in east Africa.

3.2.2. Genomics study for personalized medicine

This aims to advance personalized medicine and genome-driven diagnostic capacity. Training-of-Trainers workshop of 10 days was conducted in partnership with the University of British Columbia (UBC), Canada. The next plan is to (1) build infrastructure and human capacity for genomic study for personalised medicine; (2) conduct a pilot study with national representation of major geographic and ethnic diversity; (3) conduct large scale study; (4) support capacity for Africa. Next collaborative meeting with UBC team scheduled at the end of October while the team visits.

3.2.3. Local production of laboratory test for *Salmonella typhi*

The aim is to produce a more reliable diagnostic kit for typhoid fever testing. The project is in protocol development stage. One PhD student is engaged, and Ohio State University (USA) technically supports the project.

3.2.4. Local production of reliable TB diagnostic tools

The aim is to build capacity for local production of reliable TB diagnostic tool in Africa. The project is in collaboration with PATH (USA) and Africa CDC. Activities are awaiting approval from Africa CDC

3.2.5. Capacity for next generation sequencing

This aims to enhance and up-to-date African biomedical researchers in their capacity on genomic sequencing. The project is supported by Eastern Africa Consortium for Clinical Research (EACCR2-NID node), with funding from EDCTP. Experts from University of York, UK, provided the first round of genomics training at University of Gondar for participants selected from Eastern and Central Africa

3.2.6. Field evaluation of three devices for the diagnosis of lymphedema

The aim is to improve diagnosis of lymphedema. Portable 3D imaging system and DLP based NIR spectroscopy are being evaluated in south West Ethiopia. This is the first time these devices are being used for lymphedema related to neglected tropical diseases. A Bioimpedance technique, which will assist in determing the aetiology of the lymphedema is under development in partnership with the Brighton and Sussex Medical School and is in its final stage of development. We hope this will be ready for testing in the coming 12 months.

3.2.7. EXIT-TB project

This 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 seven health facilities (two in Addis Ababa and five in the Oromia region). Initial data collection completed and a paper has been submitted. 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. CDT-Africa's Clinical Trials Lead is the Principal Investigator of the project for Ethiopia.

3.2.8. Rapid diagnostic test for malaria

Funding has been approved for testing a new rapid malaria test, which aims to address the declining sensitivity of the existing rapid diagnostic tests in the Northern part of Ethiopia and Eritrea.

3.3.Vaccine development

The vaccine development platform requires further development. We have focused on phase IV studies and on capacity building and partnership building.

3.3. 1. Tetanus Antitoxin (TAT-Safe) trial

This is a phase IV study, which aims to evaluate the safety and kinetics of equine tetanus antitoxin, (Code: 130202084, A.W.No: 15/AAW/PI/02.00, DT: 25.04.2016, VINS Bioproducts Limited, India) when administered to adults under conditions of routine post-exposure prophylactic use in Ethiopia. The sponsor is ViNS Bioproducts Ltd (India). Additional Antivenom Phase IV study is under discussion

3.3. 2. HPV vaccine pharmacovigilance study:

This is a phase IV study that aims to evaluate the safety of HPV vaccine. This is part of a larger study called **PROFORMA**: (Pharmacovigilance infrastructure and post-marketing surveillance system capacity building for regional medicine regulatory harmonization in East Africa.) The study aims to assess current pharmacovigilance (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 is already completed and the second phase of the project has started.

3.4.Health Care Delivery Innovations

The focus on work has been on:

- Reducing maternal mortality through health systems innovation
- Scaling up care for non-communicable diseases
- Scaling up care for selected neglected tropical diseases (related to lymphedema).
- Addressing multimorbidity through horizontal integration
- Improving detection and care for tuberculosis.

These activities are supported through three relatively large projects

3.4.1. ASSET Project

This project is being implemented in partnership with King's College London. Its focus is on health systems innovation to improve care for non-communicable diseases, surgical conditions and maternal health. The first phase of the study has been completed. We have been working directly with the Federal Ministry of Health, including contribution to the Ethiopian primary health care guideline (PACK).

3.4.2. ENDPOINT

This project is being implemented in partnership with the Brighton and Sussex Medical School (BSMS). The study has two parts. The main part focuses on improving access and coverage of care for lymphedema from podoconiosis, leprosy and filariasis. The first phase of the study has been completed and is now in the middle of its second phase. The study includes a community

intervention programme to reduce stigma and enhance care utilisation. This later work is to be supported through a new project we have called IMPRESS.

- The second part of the work focuses on Scabies and is done in partnership with the Federal Ministry of Health. We are evaluating the impact of Mass Drug Administration for onchocerciasis on the incidence and prevalence of scabies. We have conducted two waves of assessment (pre and post-administration). The results are promising but not adequate.
  - As part of the scabies work, we have just embarked on evaluating potential traditional herbs for scabies. We will be recruiting a fellow to work on this work.
  - We also have a tentative plan to work on a point-of-care diagnostic tool.

3.4.3. EXIT-TB Project

Described above

3.4.4. PROFORMA

Described above

4. DLI#3: TIMELY AND TRANSPARENT FINANCIAL MANAGEMENT

While the key results are achieved (see Table below) for finance management, we will be awaiting disbursement for these results. We use the auditor within the Addis Ababa University and the College of Health Sciences. External auditing has been carried out by an independent and accredited audit firm. The financial reports have been submitted regularly and posted online.

The procurement manual has been approved by Addis Ababa University and the World Bank for use by CDT-Africa. This has conferred a good level of autonomy for the centre. Auditing of procurement has not occurred because it was not possible to find a qualified firm with reasonable price despite several advertisements.

Table 20 Financial management results

DLI#3: Timely, transparent and institutionally reviewed Financial Management ($300,000)	Disbursement amount	Achieved
3.1: Timely Withdrawal applications	$75,000 (15,000/yr)	$30,000
3.2: Functioning audit committee	$75,000 (15,000/yr)	-
3.3: Functioning internal audit unit	$75,000 (15,000/yr)	-
3.4: Transparency of financial management	$75,000 (15,000/yr)	$30,000
Total	$300,000 (5 years)	$60,000, 20% (2 years)

5. DLI#4: TIMELY AND AUDITED PROCUREMENT

Table 21 Procurement related results

DLI#3: Timely and audited Procurement ($300,000)	Disbursement amount	Achieved
4.1: Timely procurement audit report	$150,000 (30,000/yr)	-
4.2: Functioning audit committee	$150,000 (30,000/yr)	-
Total	$300,000	-

RELEVANCE OF DESIGN

It is our considered observation that the ACE project is an extremely important initiative for addressing the development challenges of Africa. For example, we know that in high income countries, such as in the US and Europe, pharmaceutical manufacturing generates billions of dollars as well as opening up an opportunity for hundreds of thousands to have well-paying jobs. Contract Research Organizations working in the area of clinical trials, one of the activities of CDT-Africa, generate billions of dollars in revenue. More broadly, a center like CDT-Africa can serve as a catalyst for biomedical innovation as well as innovation in general. As models of excellence, the ACEs have the potential to transform or at least have some modest impact on higher education quality and impact.

FIDUCIARY MATTERS

Although we started slowly, the activity of CDT-Africa has picked pace substantially. Our disbursement has reached 40% and we are awaiting verification and disbursement for another 10%. We have mobilized external funds to support our work. Currently, CDT-Africa has provided employment opportunity for 91 full time staff, which will expand further given the expanding nature of the work and the new funds mobilized. While our spending is cautious taking into consideration the need for sustainability, the overall use of fund of the World Bank and the external funds is as would be expected. All externally funded project activities support the work of one or a combination of the tasks of CDT-Africa. For example, the EnDPoINT fund supports education excellence, supporting two postdoctoral students and one doctoral fellow, and the healthcare delivery innovation and diagnostic development platforms. The ASSET fund supports all three platforms-healthcare delivery innovation, diagnostic development and regulatory capacity/clinical trials, as well as supporting education excellence supporting one postdoctoral student.

Funding for Incubation Centre: It is to be recalled that the Incubation Centre of CDT-Africa (The Africa Bio-Hub) has been recognized as a regional centre of excellence without funds. We are grateful for this recognition. With the conviction that the Africa Bio-Hub will play a crucial role for the regional goals of CDT-Africa, we have pursued the planning and the work of the Bio-Hub. As indicated, we have established an InnoCafe; we are working on several product development;

we are in the process of renovating a relatively large space to be dedicated for the medical discovery laboratory of the incubation centre; equipment are on order. We would request for a reconsideration of the funding for our incubation centre.

Financial transparency is as noted. Financial report summary is attached.

SAFEGUARDS

No safeguard measures were invoked. However, we will be requesting environmental assessment for a renovation plan for incubation centre. We are also developing a 'green strategy' considering environmental safeguards for medical discovery and development research as well as environmental sustainability, for example, in the area of energy use.

NEED FOR RESTRUCTURING

Postdoctoral program: The typical PhD graduate in Africa is assigned immediately after graduation to work in a university taking up senior responsibilities without the opportunity to grow as a scientist and leader in a mentored and protected environment. For most, this is the end of the road to academic excellence or impactful research. Our limited experience has made it clear that a postdoctoral program is an important step in transforming an aspiring graduate into a real and impactful scientist. Moreover, this is one of our strategies to develop impactful scientists and leaders for CDT-Africa. Currently, although this has been approved, is not considered a result or attract disbursement. We believe Postdoctoral program of centres should count as a result and should be encouraged with disbursement.

Accreditation: We support the requirement for regional and international accreditation. International accreditation is an important milestone for a centre of excellence and can make a centre internationally competitive and relevant. However, the fund allocation needs to be readjusted such that the disbursement for international accreditation is allocated to the national accreditation and vice versa. While we commit to continue working towards international accreditation, reallocating the funds as suggested would allow use of the funds for implementation of the centre activities while pursing international accreditation.

PhD students: Currently PhD student enrollment is considered a result only when they have their proposal approved. While we agree that this is an important milestone, it should be noted that students with heavy course work requirements take up to two years to get their protocols approved. This is financially burdensome, especially when students are non-nationals and fully sponsored. We respectfully suggest that for programs with course work requirements, PhD students have to be considered result if they completed their first year successfully. It is to be recalled that a similar suggestion was made in the Kigali and Nairobi meetings.

Sustainability and impact: We are working to lay the foundations for sustainability and impact. While the results of this work so far have been promising, time is not on our side. The remaining time for ensuring sustainability is too short. We request an extension of about a year as well as further funding opportunities as was the case for the ACE 1 projects.

Achieving excellence: It is somehow an uncomfortable truth that excellence, despite the designation of the centres, is an overlooked paradigm. Currently the focus of the ACEs is on achievement of the results in the results framework. While the framework has some provisions, such as international accreditation and PASET benchmarking, for ensuring excellence, these results have proven very difficult to achieve or even pursue. An additional or alternative framework is necessary to encourage the ACEs to pursue excellence. This may also require further structured input.

Equipment procurement: We have found procurement of specialized equipment a major challenge. Recently we put out a bid for the procurement of 48 specialized equipment; only 11 were available for purchase. This is without considering the challenge of ensuring quality of the equipment procured. Recognizing that it is impossible for the centres to be specialist centres or centres of excellence without specialist equipment, the centres would benefit from support on procuring equipment directly from the producers.

Staff exchange: While we think a minimum duration requirement is appropriate for student exchanges, this duration should not be a requirement for faculty or staff exchange. The need of staff or faculty is often around strengthening partnerships and supporting students who are in exchange programs as well as a limited exposure relevant to technology transfer. These mostly do not require an exchange duration of more than five days. We are therefore requesting respectfully that if duration should be specified, a five-day duration should be sufficient.

PASET benchmarking: As a university level responsibility, PASET benchmarking is not entirely under the control of the ACEs, at least the Ethiopia ACEs. Further guidance and support to achieve this result is required.

Regionality: Our goal is to support regional capacity using regional resources. CDT-Africa is making an effort to achieve regionality. For example, one of the agenda for the two consortium meetings was on how to strengthen regionality and regional partnership. In our first year, about 30% of expenses of CDT-Africa was on strengthening and supporting partnership. Yet, regionality remains a challenge. Technical support in this area may be helpful.

CONCLUSION

We hope that what has been set out in this report demonstrates a good start by CDT-Africa. We also hope that the report demonstrates the huge potential of the centre for regional and global impact. Achieving status of excellence and impact requires sustained effort and creative thinking by planners and implementers. It also requires guidance, commitment and a degree of risk taking from the university management, and even the government and policy makers. We believe that what has been achieved and demonstrated by CDT-Africa is an indication that the risks taken by the government of Ethiopia, MoSHE and Addis Ababa University were worth taking. We hope that there will be confidence to continue the support to CDT-Africa and strengthen its institutional semi-autonomy.

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ANNEX

Annex 1. Summary of development challenges, objectives and planned activities of CDT-Africa during proposal

Poor and inequitable access to safe and effective health interventions, including diagnostics are recognized as important development challenges for Africa, including the East Africa and Ethiopia. Among the several challenges identified in providing accessible interventions, the main ones are: (i) critical shortage of skilled manpower; (ii) focus on basic researches instead of translational and clinical researches; (iii) the growing burden from non-communicable diseases while the burden of communicable, maternal and perinatal conditions is still unresolved; (iv) the limited regulatory capacity, which extends to poor coordination among regulatory and ethics bodies. Other challenges have included: Limited capacity for pharmaco-genomic and epigenetic studies to address genetic, and environmental variation that affect therapeutic responses in the population of the region; Under developed data management capacity, particularly electronic data management systems leading to challenges in timely data monitoring and control, especially in the context of multicentre and cross-country studies; Poor clinical research-industry linkage: whereas international companies have high expectations and are not attracted to invest, local industries focus on manufacturing but pay little attention to research and development; Very limited capacity and experience in conducting therapeutic trials across the region5; Lack of economic evaluations and weak regional collaboration; Poor public engagement/community participation in research and clinical trials; Low implementation of health research outcomes perpetuating poor access and inequity; Access to simple and affordable point-of-care diagnostic tests is essential for improving therapeutic interventions, and to control diseases in both humans and animals. Many parasitic diseases are among the major public health problems for which optimal diagnostic tests are still lacking, e.g. schistosomiasis, hydatidosis, cysticercosis. Other available tests require improvements, e.g. in cutaneous and visceral leishmaniasis. There is great need for tests that assist in evaluation of treatment outcomes, assessment of prognosis, and for those that serve as markers of severity. Diagnostic tests are also needed for differential diagnosis of active versus asymptomatic infections to assist in the design of therapeutic algorithms and in planning interventions aimed at control and elimination of diseases.
Manufacturing of pharmaceuticals is considered an "untapped opportunity for inclusive and sustainable industrial development in Africa" (African Union) that might lead to "simultaneous achievement of public health and industrial development" (East African Community), which would contribute "significantly to economic growth and social development" (Ethiopia). However, for these ambitious continental, regional and national visions to become a reality, it requires; critical manpower with a mix of skills; specialized centers that support innovation and discovery; parallel growth of therapeutics and diagnostics, harnessing the opportunity offered by the rapidly evolving technology; regional collaboration; and strengthening and streamlining of regulatory processes. CDT-Africa provides an unparalleled opportunity to meet these requirements and fulfil the vision of sustainable and substantial development through ensuring access to effective and safe medicines. CDT-Africa would support development of the requisite human and facility capacity for translational research for drug discovery. Specifically, CDT-Africa would support capacity development for the key steps to make safe and effective medicines available: i. Development of novel therapeutic interventions (drugs, vaccines, diagnostics, etc.) from locally available sources (mainly natural products); (ii) Improved access of treatments for the economically disadvantaged, children and women by supporting development of appropriate interventions; (iii) Translation of the large pool of preclinical data (for example herbal medicines) available in the country and the region by creating a regional database and through further development focusing on selected natural products of high promise; (iv) Exploration of other therapeutic indications of currently available interventions (drug repurposing); (v) Evaluation of bioequivalence of locally produced generic medicines; (vii) Implementation of pharmaco-economic evaluations; (vii) support availability of skilled man power for manufacturers in the region, including direct technical support and technology (b) Develop capacity to study genetic and epigenetic variations that affect safety, therapeutic response and effectiveness (c) Develop institutional and human capacity for the conduct of clinical trials, which include: i. Establishment of a regional trials data management center of international standard through trainings, exchange, benchmarking, statistical support and capacity to use and/or innovate e-Resourcing methods; (ii) Creation of a critical mass of investigators, monitors, trainers, Data and Safety Monitoring Board experts through advanced (MSc and PhD) and short-term training programs, including internships with industry, private partners, contract research organizations, and exchange programs with international partners; (iii) Strengthening quality assured laboratories through: facility upgrade, training of laboratory personnel in good clinical laboratory practice and quality assurance schemes; (iv) Conducting training in applicable national and international regulatory laws; short-courses on health research ethics training and good clinical practice; supporting coordination of ethics and regulatory boards. (d) CDT-Africa will support training in ACE-industry and university-industry linkage, and implement strategies and plans to build and foster such links. These include; maintaining consistent high standards to attract international companies; strengthening engagement through industry-linked internships; joint training initiatives; forums for bilateral engagement with research findings; supporting research and development in local pharmaceutical industries; provide access to potential products, innovations and knowledge, and exchange technologies with industries, and mobilize relevant resources from industry. (e) CDT-Africa will support implementation of relevant research findings into policy through implementation research, engagement with policy makers from the outset by partnering with key policy makers, and increasing capacity for implementation research by providing training on implementation science as a short course and MSc track. (f) Public engagement and awareness will be promoted using various mediums and forums. We aim to form a Public Advisory Board (PAB), which includes key community or public leaders, media personnel, leaders of selected ministries, advocacy groups, patient and caregivers, individual champions and information leaflets. We will disseminate findings through peer reviewed publications and appropriate policy briefs. Within the research training program, as part of the initial situational analysis, we will study public attitudes and behaviour towards drug development, clinical trials, and traditional medicine and develop appropriate interventions to support safe and favorable attitudes and practices. (g) CDT-Africa will build capability for diagnostic test development and field evaluation in clinical trials. To this end, it is planned to set-up a biorepository for biological specimens (serum, urine, saliva, biopsy, etc.) such that innovated products will undergo preliminary screening in the laboratory prior to field testing. This facility will have a GCP-compliant biorepository scheme with detailed procedures of archiving and use by innovators, and anchored on well articulated ethical and legal provisions. CDT-Africa aims to innovate and adopt at least two point-of-care diagnostic tools. (h) Business model: Sustainable financing will be at the core of the conduct of the center and the center will develop an explicit business plan from the outset; (i) CDT-Africa will work to identify synergies between therapeutics and diagnostics as well as scientists; will work to develop or adapt products that may have applicability across disorders; will develop capacity to collect and analyze complex data http://www.unido.org/fileadmin/user_media /News/2011/Pharmaceutical%20manufacturing%20plan%20for%20Africa-English.pdf;http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2014/march/20140329ecapharmaceuticals;http://feapm.com/fileadmin/user_upload/documents/EAC_Regional_Pharmaceutical_Manufacturing_Plan_of_Action.pdf; http://www.who.int/phi/publications/Ethiopia_strategy_local_poduction.pdf; Fekadu A et al. International Clinical Trial Day and Clinical Trials in Ethiopia and Africa. Trials 2014; 15:493