PROGRAM REPORT

NOVEMBER 2021

African Consortium for Cancer Clinical Trials (AC3T)

Takeda

Submitted as part of Access Accelerated

Access Observatory

Contents

The information in this report has been submitted by the company concerned to the Access Observatory at Boston University. The information will be updated regularly. For more information about the Observatory go to www.accessobservatory.org

Program Description

Program Overview

1 Program Name

African Consortium for Cancer Clinical Trials (AC3T)

2 Diseases program aims to address

- Cancer (General)

3 Beneficiary population

- Age: All ages
- Gender: All genders
- Special Populations: People with low income

4 Countries

- Kenya
- Nigeria
- Rwanda
- Cameroon
- Cote d'Ivoire
- Senegal

5 Program start date

June 1, 2017

6 Anticipated program completion date

January 1, 2021

7 Contact person

Chris Reddick: chris.reddick@takeda.com

8 Program summary

Africa is facing an emerging cancer crisis – a crisis that kills 60% more people than malaria. Africa's burgeoning cancer crisis is attributable to many complex and interrelated factors including population growth and aging; insufficient preventive, diagnostic, and treatment services; inadequate clinical and research infrastructure; and severe shortages of trained healthcare personnel. Compounding this cancer crisis is the lack of cancer clinical trial data in African ethnicities. Oncology clinical trials are urgently needed not only to provide much needed access to new and innovative cancer therapies, but also to assess their efficacy and safety in the biologically and genetically distinct cancers and patient populations in Africa.

To address this gap and help build cancer clinical trial capacity in Africa, Takeda have partnered with NGOs BIO Ventures for Global Health (BVGH) and the African Organization for Research & Training in Africa (AORTIC), other pharmaceuticals and U.S. and African cancer centers to established a unique public-private-partnership to serve as an accelerator and center of excellence to strengthen cancer clinical trial capacity in Africa.

Launched in June 2017 under the purview of African Access initiative (AAI), The African Consortium for Cancer Clinical Trials (AC3T) program, aims to build oncology clinical trial capacity in African countries, while improving patient outcomes.

AC3T program objectives include:

- Increase access to new and established cancer medicines and technologies through clinical trials
- Address the cancer data gap in African ethnicities
- Identify and empower African cancer centers and hospitals that are "ready now" to conduct and participate in cancer clinical trials
- Galvanize support for African investigator-led cancer clinical trials in local patient populations, with treatment scenarios that address local unmet needs
- Strengthen clinical trial capacity in "soon to be ready" cancer centers and hospitals.

AC3T brings together AAI stakeholders including government and non-governmental organizations, the AORTIC, leading oncologists, and multinational pharmaceutical companies to create coherence and leverage capabilities and initiatives to empower African clinicians and primary investigators to strengthen clinical trial capacity in Africa. In order to do this successfully and drive sustainability the programs activities include:

Program Overview

8 Program summary, cont.

- Needs Assessments - AAI Hospital Needs Assessments ensure that AAI and AC3T are driven by Africa, for Africa by generating country-level data on cancer burden and current practices, treatment gaps, capacity building needs, and technology and drug priorities

- Mapping Capacity - data gathered from completed Needs Assessments and AC3T Checklists map hospital capacity and define AAI and AC3T priorities. These include lists of ongoing and planned cancer clinical trials in Africa with special focus on the African countries selected to participate in AAI

- AC3T Checklists - assess a hospital's cancer clinical trial infrastructure, experience, and "readiness."

- Training - through the needs and mapping assessments, training plans and resources to support clinical trial capacity building are mapped and subsequently put into place.

The AC3T program is currently active in Kenya, Rwanda, Nigeria, Cameroon, Senegal, Cote d'Ivoire and through the robust needs assessments a number of capacity building efforts are underway with local partners:

1. Strengthening Diagnostic Laboratories

- Nigeria's Federal Medical Center is enhancing its diagnostic pathology laboratory with five high-value instruments donated by an industry partner

- The pathology laboratory at the University Teaching Hospital of Kigali in Rwanda is advancing towards the achievement of international accreditation with the support of an industry partner

2. Building Clinical Oncology and Research Expertise

- Cameroon's Bonassama District Hospital is augmenting its breast cancer surgery and hematology capabilities with training from academic oncology experts

- Côte d'Ivoire is addressing the high burden of prostate cancer in Africa through its participation in a multinational research consortium

- Moi Teaching & Referral Hospital in Kenya is increasing its cancer clinical trial site appeal with the guidance of an industry partner

3. Expanding Access to Treatment Through Clinical Trials

- Hospitals across Africa are completing AC3T Checklists to define their cancer clinical trial capabilities, experience, and needs

- Through the AC3T RFI, African investigators are disclosing their interest in conducting cancer clinical trials

- The AC3T Study Pool, which will fund investigator-initiated cancer clinical trials in Africa, is in development

The strength of the AC3T program is in its partners, who all contribute to the objective and effectiveness in different ways. Takeda R&D and other partners provide funding to the coordinating NGO (BVGH) to manage the Program, identify unmet needs and gaps in clinical trial capacity in LMICs through assessments and oversee delivery of the objectives.

The AC3T Steering Committee is led by BVGH in partnership with AORTIC, and comprised of NGO, University and Pharma partners. The cancer centers in the respective LMICs are fundamental as they develop and implement cancer research projects in respective LMIC, coordinate and communicate with local stakeholders including Ministry of Health and develop sustainability plans for continued cancer center growth. Takeda R&D and other partners also fund the study pool to support cancer clinical research projects submitted by LMICs in SSA and support assessments to identify unmet needs and gaps in clinical trial capacity in LMICs.

Clinical trial capabilities are critical to providing long-term, sustainable healthcare in LMICs and enable LMICs to address specific medical and scientific questions impacting their patient populations from within. Through the AC3T program, the current data gap in African countries is beginning to be addressed and more importantly, African cancer centers and hospitals that are "ready now" to conduct and participate in cancer clinical trials are empowered to do so. In the long-term this will enable LMICs to apply for and receive research grants from national and international bodies as well as participate in global cancer clinical trials of new medicines and technologies. This in turn allows hospitals/universities in LMICs to attract and retain scientific talent, invest in the growth of their cancer departments and train the next generation of cancer researchers.

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Health Service Strengthening

ACTIVITY	DESCRIPTION
Training	AC3T will increase access to new and established cancer diagnostics, medicines, and treatments through clinical trials while building clinical trial capacity and addressing the cancer data gap in Africa. Takeda R&D employees will share their scientific and technical expertise with cancer researchers within the AC3T network to address identified gaps and capacity building needs. The AC3T Steering Committee led by BVGH and comprised of NGO, University and Pharma partners will work hand in hand with Cancer centres to develop and implement cancer research projects in respective LMIC.
Infrastructure	Through the AC3T initiative, we hope to support and strengthen the health system as follows: - Increase access to new and established cancer medicines and technologies through clinical trials - Address the cancer data gap in African ethnicities. - Identify and empower African cancer centers and hospitals that are "ready now" to conduct and participate in cancer clinical trials. - Galvanize support for African investigator-led cancer clinical trials in local patient populations, with treatment scenarios that address local unmet needs. - Strengthen clinical trial capacity in "soon to be ready" cancer centers and hospitals
Technology	Takeda R&D employee's will provide technical skills and know-how while AC3T partners will contribute the following: - AC3T check-list to access cancer clinical trial gaps and readiness. - AC3T database/listing of ongoing and planned cancer clinical trials in Africa with special focus on the African countries selected to participate in AAI. - AC3T on-line profile of African cancer centers capabilities to conduct cancer clinical trials.
Other: Research Support	Through the AC3T initiative, we hope to support and strengthen the health system as follows: - Increase access to new and established cancer medicines and technologies through clinical trials - Address the cancer data gap in African ethnicities. - Identify and empower African cancer centers and hospitals that are "ready now" to conduct and participate in cancer clinical trials. - Galvanize support for African investigator-led cancer clinical trials in local patient populations, with treatment scenarios that address local unmet needs. - Strengthen clinical trial capacity in "soon to be ready" cancer centers and hospitals.

10 Strategy by country

[No response provided]

Companies, Partners & Stakeholders

11 Company roles

COMPANY	ROLE
Takeda	• Takeda R&D and other partners provide funding to the coordinating NGO (BVGH) to manage the AC3T Program and oversee delivery of the objectives. • Takeda R&D and other partners provide funding into the study pool to support cancer clinical research projects submitted by LMICs in SSA. • Support assessments to identify unmet needs and gaps in clinical trial capacity in LMICs. • Takeda R&D employees share their scientific and technical expertise with cancer researchers within the AC3T network to address identified gaps and capacity building needs.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Bio Ventures Global Health	• Manage the AC3T Program and oversee delivery of program objectives • Lead and coordinate the AC3T Steering Committee • Identify unmet needs and gaps in clinical trial capacity in LMICs through assessments. https://bvgh.org/	Voluntary
African Organization for Research & Training in Cancer (AORTIC)	• Co-lead and coordinate the AC3T Steering Committee • Coordinate and communicate with SSA countries and stakeholders. https://aortic- africa.org/	Voluntary
Cancer centres in LMICs	• Develop and implement cancer research projects in respective LMIC and • Coordinate and communicate with local stakeholders including Ministry of Health • Develop sustainability plans for continued cancer center growth.	Public

13 Funding and implementing partners by country

[No response provided]

Local Context, Equity & Sustainability

15 Local health needs addressed by program

Africa is facing an emerging cancer crisis – a crisis that kills 60% more people than malaria. Africa's burgeoning cancer crisis is attributable to many complex and interrelated factors including population growth and aging; insufficient preventive, diagnostic, and treatment services; inadequate clinical and research infrastructure; and severe shortages of trained healthcare personnel. These factors combined result in a 70% mortality rate in African cancer patients – double that of cancer patients in the United States.

Compounding this cancer crisis is the lack of cancer clinical trial data in African ethnicities. Research has highlighted the mortality gap between Caucasian and African American cancer patients, with inherent biological and genetic tumor differences contributing to this discrepancy. Oncology clinical trials are urgently needed not only to provide much needed access to new and innovative cancer therapies, but also to assess their efficacy and safety in the biologically and genetically distinct cancers and patient populations in Africa.

• The National Comprehensive Cancer Network (NCCN) believes that "the best management for any patient with cancer is in a clinical trial."

• US FDA estimated that only 4% of patients enrolled in a successful cancer clinical trial in 2018 were of African descent.

• Less than 2% of cancer studies listed in ClinicalTrials.gov were performed in Africa.

• Individuals of African descent have unique, intrinsic tumor genetics and biologies compared to individuals of European descent.

• Studies have demonstrated an inverse correlation between drug resistance and susceptibility of lung cancer patients of European vs. African descent.

• Lack of cancer clinical trial data in African ethnicities is well recognized and research has highlighted the mortality gap between Caucasian and African American cancer patients. Cancer clinical trials are urgently needed to provide access to new and innovative cancer therapies and to assess their efficacy and safety in Africa's biologically and genetically-distinct cancers and patient population.

To address the unmet need, Takeda and BVGH along with other pharmaceutical and NGO partners and U.S. and African cancer centers have established a unique public-private-partnership to serve as an accelerator and center of excellence to strengthen cancer clinical trial capacity in Africa .

The African Consortium for Cancer Clinical Trials (AC3T) initiatives' aim is to build oncology clinical trial capacity in African countries, while improving patient outcomes. AC3T will increase access to new and established cancer diagnostics, medicines, and treatments through clinical trials while building clinical trial capacity and addressing the cancer data gap in Africa. AC3T will bring together AAI stakeholders including government and non-governmental organizations, the African Organization for Research and Training in Cancer (AORTIC), leading oncologists, and multinational pharmaceutical companies to create coherence and leverage capabilities and initiatives to empower African clinicians and primary investigators and to strengthen clinical trial capacity in Africa.

Local Context, Equity & Sustainability

18 How diversion of resources from other public health priorities are avoided

[No response provided]

19 Program provides health technologies (medical devices, medicines, and vaccines)

No.

20 Health technology(ies) are part of local standard treatment guidelines

N/A

21 Health technologies are covered by local health insurance schemes

N/A

22 Program provides medicines listed on the National Essential Medicines List

N/A

23 Sustainability plan

The overarching aim of AC3T is to build oncology clinical trial capacity in African countries, while improving patient outcomes. AC3T will increase access to new and established cancer diagnostics, medicines, and treatments through clinical trials while building clinical trial capacity and addressing the cancer data gap in Africa.

To do this, it is critical to involve key country stakeholders and governments from the outset and in the development of the initiative. As such the AC3T is designed to bring together AAI stakeholders including government and non-governmental organizations, the African Organization for Research and Training in Cancer (AORTIC), leading oncologists, and multinational pharmaceutical companies to create coherence and leverage capabilities and initiatives to empower African clinicians and primary investigators and to strengthen clinical trial capacity in Africa. Only though multi-stakeholder collaboration and partners on the ground can we ensure to address the cancer data gap in African ethnicities and strengthen clinical trial capacity in "soon to be ready" cancer centers and hospitals.

Clinical trial capabilities are critical to providing long-term, sustainable healthcare in LMICs. Strengthening this enables LMICs to address specific medical and scientific questions impacting their patient populations from within, allows LMICs the opportunity to apply for and receive research grants from national and international bodies as well as participate in global cancer clinical trials of new medicines and technologies. This in turn allows hospitals/universities in LMICs to attract and retain scientific talent, invest in the growth of their cancer departments and train the next generation of cancer researchers.

Companies, Partners & Stakeholders

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT	REQUESTED OR RECEIVED FROM STAKEHOLDER
Government	Through partners, the program ensures Government remains aligned with activities.	Infrastructure: No Human Resources: No Funding: No Monitoring or Oversight: No Other resource: No
Non-governmental organization (NGO)	• manage the AC3T Program and oversee delivery of program objectives • lead and coordinate the AC3T Steering Committee • identify unmet needs and gaps in clinical trial capacity in LMICs through assessments • Coordinate and communicate with SSA countries and stakeholders	Infrastructure: No Human Resources: Yes Funding: Yes Monitoring or Oversight: Yes Other resource: No
Local hospitals/ health facilities	Cancer centers in LMICs • Develop and implement cancer research projects in respective LMIC and • Coordinate and communicate with local stakeholders including Ministry of Health • Develop sustainability plans for continued cancer center growth	Infrastructure: Yes Human Resources: Yes Funding: No Monitoring or Oversight: Yes Other resource: No
Local universities	Cancer centers in LMICs (including University Hospitals) • Develop and implement cancer research projects in respective LMIC and • Coordinate and communicate with local stakeholders including Ministry of Health • Develop sustainability plans for continued cancer center growth	Infrastructure: Yes Human Resources: Yes Funding: No Monitoring or Oversight: Yes Other resource: No

Local Context, Equity & Sustainability

15 Local health needs addressed by program, cont.

Clinical trial capabilities are critical to providing long-term, sustainable healthcare in LMICs. Strengthening this enables LMICs to address specific medical and scientific questions impacting their patient populations from within, allows LMICs the opportunity to apply for and receive research grants from national and international bodies as well as participate in global cancer clinical trials of new medicines and technologies. This in turn allows hospitals/universities in LMICs to attract and retain scientific talent, invest in the growth of their cancer departments and train the next generation of cancer researchers.

a How needs were assessed

BVGH, is responsible for identifying unmet needs and gaps in clinical trial capacity in LMICs through country assessments, onsite visits and discussions with stakeholders.

b Formal needs assessment conducted

Yes

16 Social inequity addressed

[No response provided]

17 Local policies, practices, and laws considered during program design

POLICY, PRACTICE, LAW	APPLICABLE TO PROGRAM	DESCRIPTION OF HOW IT WAS TAKEN INTO CONSIDERATION
National regulations	Yes	The program is being coordinated and delivered in partnership with AORTIC and local cancer centres to ensure the program is in line with local policies and practices.
Quality and safety requirements	No	[No response provided.]

Additional Program Information

24 Additional program information

No additional information provided.

a Potential conflict of interest discussed with government entity

Yes.

25 Access Accelerated Initiative participant

Yes

26 International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) membership

Yes

Program Indicators

PROGRAM NAME

African Consortium Cancer Clinical Trials (AC3T)

27 List of indicator data to be reported into Access Observatory database

	INDICATOR	TYPE	STRATEGY	2019	2020
1	Number of unique patients enrolled in clinical trials	Outcome	Health service strengthening	---	---
2	Number of people trained	Output	Health service strengthening	---	---
3	Equipment in use	Output	Health service strengthening	---	---
4	Value of funding provided	Output	Health service strengthening	---	---
5	Value of resources	Input	All program strategies	---	---
6	Staff time	Input	All program strategies	---	---

INDICATOR

Number of unique patients enrolled in clinical trials

1

STRATEGY HEALTH SERVICE STRENGTHENING

	ITEM	DESCRIPTION
	Definition	The number of unique patients enrolled in clinical trials implemented through program activities.
	Method of measurement	The sum of the number of unique patients enrolled in clinical trials
28	Data source	Routine program data
29	Frequency of reporting	Once per year

		RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30	Data collection	Bio Ventures Global Health, African Organization for Research & Training in Cancer (AORTIC), Cancer centres in LMICs.	Our implementing partners, independent, external third party organizations keep records of the number of unique patients enrolled in clinical trials.	Ongoing
31	Data processing	Bio Ventures Global Health, African Organization for Research & Training in Cancer (AORTIC), Cancer centres in LMICs and Company: Takeda.	Data is reviewed by each of the implementing partners. Information is then consolidated and reviewed by Takeda's Access to Medicines Research and Development team.	Every 6 months
32	Data validation		A review of our implementing partner is performed annually / every two years.	

33 Challenges in data collection and steps to address challenges.

[No response provided]

INDICATOR		2019	2020
1	Number of unique patients enrolled in clinical trials	---	---

Comments: N/A.

INDICATOR **Number of people trained**

STRATEGY HEALTH SERVICE STRENGTHENING

2

	ITEM	DESCRIPTION
	Definition	Number of trainees
	Method of measurement	Counting of people who completed all training requirements Calculation: Sum of the number of people trained
28	Data source	Routine program data, External non-public data
	Frequency of reporting	Once per year

		RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30	Data collection	Implementing partners: Bio Ventures Global Health, African Organization for Research & Training in Cancer (AORTIC), Cancer centres in LMICs.	Our implementing partners, independent, external third party organizations keep record of the number of the number of people trained.	Ongoing
31	Data processing	Implementing partners: Bio Ventures Global Health, African Organization for Research & Training in Cancer (AORTIC), Cancer centres in LMICs, Company: Takeda.	Data is reviewed by each of the implementing partners. Information is then consolidated and reviewed by Takeda's Access to Medicines Research and Development team.	Ongoing
32	Data validation		Data on the number of researchers at sites that have been trained by Takeda and the implementing partner will be collected and reported by the partner on an annual basis Takeda validates the data set through interactions a number of ways: 1) monthly calls with the implementing partner, 2) monthly calls with sites receiving instrumentation (as part of the mentoring and training component of the program), 3) site representatives visit Takeda annually to present on how they are using the donated equipment and on the progress of their research and 4) visits to sites every 2 years.	

INDICATOR Number of people trained

STRATEGY HEALTH SERVICE STRENGTHENING

2

33 Challenges in data collection and steps to address challenges.

[No response provided]

INDICATOR	2019	2020
2 Number of clinical trials	---	---

Comments: N/A.

INDICATOR **Equipment in use**

STRATEGY HEALTH SERVICE STRENGTHENING

3

	ITEM	DESCRIPTION
	Definition	Number of equipment donated or supplied and in use
	Method of measurement	The number of equipment which are in use Calculation: Sum of the numerical count of equipment in use
28	Data source	Routine program data
29	Frequency of reporting	Once per year

		RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30	Data collection	Implementing partner: Bio Ventures Global Health, African Organization for Research & Training in Cancer (AORTIC), Cancer centres in LMICs.	Our implementing partners, independent, external third party organizations keep record of the equipment in use.	Ongoing
31	Data processing	Implementing partners: Bio Ventures Global Health, African Organization for Research & Training in Cancer (AORTIC), Cancer centres in LMICs.	Data is reviewed by each of the implementing partners. Information is then consolidated and reviewed by Takeda's Access to Medicines Research and Development team.	Ongoing
32	Data validation		A review of our implementing partner is performed annually / every two years.	

33 Challenges in data collection and steps to address challenges.

[No response provided]

INDICATOR	2019	2020
3 Equipment in use	---	---

Comments: N/A.

INDICATOR **Value of funding provided**

STRATEGY HEALTH SERVICE STRENGTHENING

4

	ITEM	DESCRIPTION
	Definition	Total amount of awards disbursed by the company for a specific activity which form part of the program. This is distinct from the total amount invested in the program (see Input Expenditure)
	Method of measurement	Total amount of money disbursed through funding activities Calculation: Sum of the total amount of money disbursed to implementing partner
28	Data source	Routine program data
29	Frequency of reporting	Once per year

		RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30	Data collection	Bio Ventures Global Health, African Organization for Research & Training in Cancer (AORTIC), Cancer centres in LMICs.	Our implementing partners, independent, external third party organizations keep record of the number of the value of funded provided. The implementing partner is responsible for processing programmatic financial data at the individual site level (those sites receiving research funding). Takeda collects and reports financials related to payments to the partner to run and administer the overall program.	Once per year
31	Data processing	Bio Ventures Global Health, African Organization for Research & Training in Cancer (AORTIC), Cancer centres in LMICs, and Company: Takeda.	Data is reviewed by each of the implementing partners. Information is then consolidated and reviewed by Takeda's Access to Medicines Research and Development team.	Ongoing

INDICATOR **Value of funding provided**

STRATEGY HEALTH SERVICE STRENGTHENING

4

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
32 Data validation	Takeda	Takeda validates the data set through interactions a number of ways: 1) monthly calls with the implementing partner, 2)monthly calls with sites receiving instrumentation (as part of the mentoring and training component of the program), 3) site representatives visit Takeda annually to present on how they are using the donated equipment and on the progress of their research and 4)visits to sites every 2 years.	

33 Challenges in data collection and steps to address challenges

[No response provided]

INDICATOR	2019	2020
4 Value of funding provided	---	---

Comments:

INDICATOR **Value of resources**

STRATEGY ALL PROGRAM STRATEGIES

5

	ITEM	DESCRIPTION
	Definition	Total expenditure by company to operate program, including all expenditures that can reasonably be defined as necessary to operate the program
	Method of measurement	Program administrative records or accounting or tax records provide details in the expenditures on the program in a defined period of time Calculation: Sum of expenditures (e.g., staff, materials) on program in US$
28	Data source	Routine program data
29	Frequency of reporting	Once per year

		RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30	Data collection	Bio Ventures Global Health, African Organization for Research & Training in Cancer (AORTIC), Cancer centres in LMICs.	The implementing partner is responsible for processing programmatic financial data at the individual site level (those sites receiving research funding). Takeda collects and reports financials related to payments to the partner to run and administer the overall program.	Ongoing
31	Data processing	Bio Ventures Global Health, African Organization for Research & Training in Cancer (AORTIC), Cancer centres in LMICs.	Data is reviewed by each of the implementing partners. Information is then consolidated and reviewed by Takeda's Access to Medicines Research and Development team.	Ongoing
32	Data validation		A review of our implementing partner is performed annually.	

33 Challenges in data collection and steps to address challenges

[No response provided]

INDICATOR	2019	2020
5 Value of resources	---	---

INDICATOR **Staff time**

STRATEGY ALL PROGRAM STRATEGIES

6

	ITEM	DESCRIPTION
	Definition	The ratio of the total number of paid hours during a year by the number of working hours in that period. This indicator excludes the time of volunteers or staff time for external partners
	Method of measurement	The ratio is also called Full Time Equivalent (FTE) Calculation: Sum of the number of paid hours per year/ Total number of working hours per year
28	Data source	Routine Program Data
	Frequency of reporting	Once per year

		RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30	Data collection	Bio Ventures Global Health, African Organization for Research & Training in Cancer (AORTIC), Cancer centres in LMICs, and Company: Takeda.	Our implementing partners, independent, external third party organizations keep record of the staff and volunteer time.	Ongoing
31	Data processing	Bio Ventures Global Health, African Organization for Research & Training in Cancer (AORTIC), Cancer centres in LMICs .	Data is reviewed by each of the implementing partners. Information is then consolidated and reviewed by Takeda's Access to Medicines Research and Development team.	Ongoing
32	Data validation		A review of our implementing partner is performed annually / every two years.	

33 Challenges in data collection and steps to address challenges

[No response provided]

INDICATOR	2019	2020
6 Staff time		---

Comments: N/A

Program Documents

Program Documents

1. African Access Initiative. African Consortium for Cancer Clinical Trials (AC^3T) Brochure. Available at: https://bit.ly/aai_ac3t

Appendix

This program report is based on the information gathered from the Access Observatory questionnaire below.

Program Description

PROGRAM OVERVIEW

1 Program Name

2 Diseases program aims to address:

Please identify the disease(s) that your program aims to address (select all that apply).

3 Beneficiary population

Please identify the beneficiary population of this program (select all that apply).

4 Countries

Please select all countries that this program is being implemented in (select all that apply).

5 Program Start Date

6 Anticipated Program Completion Date

7 Contact person

On the public profile for this program, if you would like to display a contact person for this program, please list the name and email address here (i.e. someone from the public could email with questions about this program profile and data).

8 Program summary

Please provide a brief summary of your program including program objectives (e.g., the intended purposes and expected results of the program; if a pilot program, please note this). Please provide a URL, if available. Please limit replies to 750 words.

PROGRAM STRATEGIES & ACTIVITIES

9 Strategies and activities

Based on the BUSPH Taxonomy of Strategies, which strategy or strategies apply to your program (please select all that apply)?

10 Strategy by country

If you have registered one program for multiple countries, this question allows you to provide a bit more specificity about each country (e.g. some countries have different strategies, diseases, partners, etc.). Please complete these tables as applicable.
For each portion you have you selected from above (program strategies), please identify which country/countries these apply.

COMPANIES, PARTNERS AND STAKEHOLDERS

11 Company roles

Please identify all pharmaceutical companies, including yours, who are collaborating on this program:

What role does each company play in the implementation of your program?

12 Funding and implementing partners

Please identify all funding and implementing partners who are supporting the implementation of this program (Implementing partners is defined as either an associate government or non-government entity or agency that supplements the works of a larger organization or agency by helping to carry out institutional arrangements in line with the larger organization's goals and objectives.)

a. What role does each partner play in the implementation of your program? Please give background on the organization and describe the nature of the relationship between the organization and your company. Describe the local team's responsibilities
for the program, with reference to the program strategies and activities. (response required for each partner selected).

b. For each partner, please categorize them as either a

Public Sector, Private Sector, or Voluntary Sector partner. (Public Sector is defined as government; Private Sector is defined as A business unit established, owned, and operated by private individuals for profit, instead of by or for any government or
its agencies. Generation and return of profit to its owners or shareholders is emphasized; Voluntary Sector is defined as Organizations whose purpose is to benefit and enrich society, often without profit as a motive and with little or no government intervention. Unlike the private sector where the generation
and return of profit to its owners is emphasized, money raised or earned by an organization in the voluntary sector is usually invested back into the community or the organization itself (ex. Charities, foundations, advocacy groups etc.))

c. Please provide the URL to the partner organizations' webpages

13 Funding and implementing partners by country

If you have registered one program for multiple countries, this question allows you to provide a bit more specificity about each country (e.g., some countries have different strategies, diseases, partners, etc.). Please complete these tables as applicable. For each portion you have you selected from above (funding and implementing partners), please identify which country/countries these apply.

14 Stakeholders

Please describe how you have engaged with any of these local stakeholders in the planning and/or implementation of this program. (Stakeholders defined as individuals or entities who are involved in or affected by the execution or outcome of a project and may have influence and authority to dictate whether a project is a success or not (ex. Ministry of Health, NGO, Faith-based organization, etc.). Select all that apply.

- Government, please explain
- Non-Government Organization (NGO), please explain
- Faith-based organization, please explain
- Commercial sector, please explain
- Local hospitals/health facilities, please explain
- Local universities, please explain
- Other, please explain

LOCAL CONTEXT, EQUITY & SUSTAINABILITY

15 Local health needs addressed by program

Please describe how your program is responsive to local health needs and challenges (e.g., how you decided and worked together with local partners to determine that this program was appropriate for this context)?

a How were needs assessed

b Was a formal need assessment conducted

(Yes/No) If yes, please upload file or provide URL.

16 Social inequity addressed

Does your program aim to address social inequity in any way (if yes, please explain). (Inequity is defined as lack of fairness or justice. Sometime 'social disparities,' 'structural barriers' and 'oppression and discrimination' are used to describe the same phenomenon. In social sciences and public health social inequities refer to the systematic lack of fairness or justice related to gender, ethnicity, geographical location and religion. These unequal social relations and structures of power operate to produce experiences of inequitable health outcomes, treatment and access to care. Health and social programs are often designed with the aim to address the lack of fairness and adjust for these systematic failures of systems or policies.*)

*Reference: The definition was adapted from Ingram R et al. Social Inequities and Mental Health: A Scoping Review. Vancouver: Study for Gender Inequities and Mental Health, 2013.

17 Local policies, practices, and laws considered during program design

How have local policies, practices, and laws (e.g., infrastructure development regulations, education requirements, etc.) been taken into consideration when designing the program?

18 How diversion of resources from other public health priorities are avoided

Please explain how the program avoids diverting resources away from other public health priorities? (e.g. local human resources involved in program implementation diverted from other programs or activities).

19 Program provides health technologies

Does your program include health technologies (health technologies include medical devices, medicines, and vaccines developed to solve a health problem and improve quality of lives)? (Yes/No)

20 Health technology(ies) are part of local standard treatment guidelines

Are the health technology(ies) which are part of your program part of local standard treatment guidelines? (Yes/No) If not, what was the local need for these technologies?

21 Health technologies are covered by local health insurance schemes

Does your program include health technologies that are covered by local health insurance schemes? (Yes/No) If not, what are the local needs for these technologies?

22 Program provides medicines listed on the National Essential Medicines List

Does your program include medicines that are listed on the National Essential Medicines List? (Yes/No) If not, what was the local need for these technologies?

23 Sustainability plan

If applicable, please describe how you have planned for sustainability of the implementation of your program (ex. Creating a transition plan from your company to the local government during the development of the program).

ADDITIONAL PROGRAM INFORMATION

24 Additional program information

Is there any additional information that you would like to add about your program that has not been collected in other sections of the form?

a Potential conflict of interest discussed with government entity

Have you discussed with governmental entity potential conflicts of interest between the social aims of your program and your business activities? (Yes/No) If yes, please provide more details and the name of the government entity.

25 Access Accelerated Initiative participant

Is this program part of the Access Accelerated Initiative? (Yes/No)

26 International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) membership

Is your company a member of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)? (Yes/No)

Program Indicators

INDICATOR DESCRIPTION

27 List of indicator data to be reported into Access Observatory database

For this program, activities, please select all inputs and impacts for which you plan to collect and report data into this database.

28 Data source

For this indicator, please select the data source(s) you will rely on.

29 Frequency of reporting

Indicate the frequency with which data for this indicator can be submitted to the Observatory.

30 Data collection

a. Responsible party: For this indicator, please indicate the party/parties responsible for data collection.

b. Data collection — Description: Please briefly describe the data source and collection procedure in detail.

c. Data collection — Frequency: For this indicator, please indicate the frequency of data collection.

31 Data processing

a. Responsible party: Please indicate all parties that conduct any processing of this data.

b. Data processing— Description: Please briefly describe all processing procedures the data go through. Be explicit in describing the procedures, who enacts them, and the frequency of processing.

c. Data processing — Frequency: What is the frequency with which this data is processed?

32 Data validation

Description: Describe the process (if any) your company uses to validate the quality of the data sent from the local team.

33 Challenges in data collection and steps to address challenges

Please indicate any challenges that you have in collecting data for this indicator and what you are doing to address those challenges.