

APRIL 2020

ACTION ON FISTULA™

Astellas

Submitted as part of Access Accelerated

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The information in this report has been submitted by the company concerned to the Access Observatory as part of its commitment to Access Accelerated. The information will be updated regularly. For more information about the Access Observatory go to www.accessobservatory.org

The information contained in this report is in the public domain and should be cited as: Astellas, ACTION ON FISTULA™ (2020), Access Observatory Boston, US 2020 (online) available from www.accessobservatory.org

Program Description

Program Overview

1 Program Name

ACTION ON FISTULA™

2 Diseases program aims to address

- Other NCD (Obstetric Fistula)

3 Beneficiary population

- Women
- People with low income
- Elderly (>65 yrs), Adults (15-64), Adolescents (5-14).
- Marginalized/indigenous people
- Rural Populations
- Vulnerable individuals in need of treatment

4 Countries

- Kenya

5 Program start date

May 1st, 2014

6 Anticipated program completion date

June 30, 2020

7 Contact person

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8 Program summary

ACTION ON FISTULA™, supported by a grant from Astellas Pharma Europe Ltd., an affiliate of Astellas Pharma Inc., (collectively referred to as “Astellas”), is a programme set up by the Fistula Foundation in 2014 to transform the lives of more than 1,200 women in Kenya living with fistula. This was Phase I of ACTION ON FISTULA™.

Now in phase II, grant funding to date is of €2.25 million from Astellas Pharma Europe. It is being used to transform the lives of 4,500 women in Kenya suffering due to obstetric fistula by identifying and treating the condition as well as supporting those who receive the surgical intervention throughout their treatment journey. In addition, the program aims to significantly increase the number of qualified surgeons with fistula repair skills, and increase the number of nurses trained in obstetric fistula care. ACTION ON FISTULA™ focuses on four main areas:

1. Innovative Community Outreach:

Action on Fistula™ formed partnerships with media houses in Kenya who broadcast fistula messages on the radio, reaching areas across the country. The radio spots have included prerecorded public service announcements, as well as live talk shows where callers can phone in to get more information. This approach has led to increased awareness of fistula and has been responsible for some of the patients’ referrals. Additionally, health care providers are sensitized on fistula signs and symptoms and referral methods, enhancing awareness at health centers close to where women live.

2. Surgeons and Community Health Volunteers Training:

Action on Fistula™ trains surgeons who are certified at International Federation of Gynaecology and Obstetrics (FIGO) Standard and continue to strengthen their skills with ongoing training opportunities. Action on Fistula funded the upgrade of Gynocare Women’s and Fistula Hospital to a new state-of-the-art hospital, which was inaugurated on October 5, 2016, enabling more local surgeons to receive training closer to home in eastern Africa. Additionally, ACTION ON FISTULA™ trains Community Health Volunteers on how to identify and refer fistula patients.

Program Overview

8 Program summary cont.

3. A Collaborative Network of Fistula Hospitals:

ACTION ON FISTULA™ supports the sharing of resources and referrals among fistula treatment hospitals which are equipped with operating equipment and surgical supplies by ACTION ON FISTULA™. Six treatment centers located in Kitale, Eldoret, Kisumu, Kisii, Nairobi, and Mombasa are working efficiently to provide regular fistula repair surgery.

4. Screening, Surgery, and Post-surgery Care:

Action on Fistula™ has a hotline for screening potential fistula patients. The hotline operator screens each potential fistula patient and, if they meet the threshold for referral from the screening tool score, refers the patient to the nearest ACTION ON FISTULA™ treatment center. The patient receives surgery and post-surgery care at the treatment centers.

THE ACTION ON FISTULA™ website can be found at: <https://www.astellas.com/eu/responsibility/action-on-fistula>

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Community Awareness and Linkage to Care

ACTIVITY	DESCRIPTION
Communication	ACTION ON FISTULA™ conducts outreach activities and community members are reached with fistula messages. ACTION ON FISTULA™ formed partnerships with media houses in Kenya who broadcast fistula messages on the radio, reaching areas across the country. The radio spots have included prerecorded public service announcements, as well as live talk shows where callers can phone in to get more information. This approach has been responsible for some of the patients' referrals.

Strategy 2: Health Service Strengthening

ACTIVITY	DESCRIPTION
Training	ACTION ON FISTULA™ trains surgeons who are certified at International Federation of Gynaecology and Obstetrics (FIGO) Standard and Advanced Levels and continue to strengthen their skills with ongoing training opportunities. In addition, health care providers are sensitized on fistula signs and symptoms and referral methods, enhancing awareness at health centers close to where women live. Finally, ACTION ON FISTULA™ trains Community Health Volunteers.
Infrastructure	ACTION ON FISTULA™ upgraded a local hospital to a state-of-the-art treatment hospital, where local surgeons receive training. We also support fistula treatment centers that provide regular fistula repair surgery.

Strategy 3: Health Service Delivery

ACTIVITY	DESCRIPTION
Screening	Action on Fistula™ has a hotline for screening potential fistula patients. The hotline operator screens each potential fistula patient and, if they meet the threshold for referral from the screening tool score, refers the patient to the nearest ACTION ON FISTULA™ treatment center.
Treatment	ACTION ON FISTULA™ provides fistula repair surgery for women in Kenya.

10 Strategy by country

STRATEGY	COUNTRY
Community Awareness and Linkage to Care	Kenya
Health Service Strengthening	Kenya
Health Service Delivery	Kenya

Companies, Partners & Stakeholders

11 Company roles

COMPANY	ROLE
Astellas	ACTION ON FISTULA™ was conceived, built and is run by Fistula Foundation. It was started in 2014 by a grant given to Fistula Foundation from an affiliate of Astellas Pharma Inc., Astellas Pharma Europe Ltd. (with Astellas Pharma Inc. collectively referred to as “Astellas”). Astellas is one of many sponsors/supporters of ACTION ON FISTULA™. Fistula Foundation and Astellas jointly funded Phase I of the program, 2014-2017. Astellas is funding approximately 25% of the second phase of the program running from 2017-2020. ACTION ON FISTULA™ is backed by the Astellas senior management team including DR Kemji Yasukawa, President and CEO and Mr Yukio Matsui, Chief Commercial Officer, who both visited Kenya in October 2016 to learn more about the programme and hear first-hand from women waiting for fistula surgery treatment.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Fistula Foundation	The Fistula Foundation coordinates delivery of all aspects of the Action on Fistula™ programme in Kenya, including training of fistula surgeons and a major outreach programme. Fistula Foundation has a project director on the ground in Kenya responsible for day-day management of the programme. https://www.fistulafoundation.org/	Voluntary

13 Funding and implementing partners by country

PARTNER	COUNTRY
Fistula Foundation	Kenya

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT
Government	ACTION ON FISTULA™'s community programmes work in-line with the Kenyan Ministry of Health's community strategy, focusing on training community health workers that will spread awareness about fistula and identify, support and refer women suffering from an obstetric fistula to the nearest Fistula Treatment Network facility.
Non-governmental organization (NGO)	ACTION ON FISTULA™ has partnerships with local Kenyan Community-Based Organisations (CBOs) and NGOs to conduct comprehensive community outreach programmes. It works in partnership with local community-based organisations and NGO's that are respected and trusted within their communities. It also engages “county mobilisers” who are committed individuals trained through ACTION ON FISTULA™ and then engaged to conduct regular mobilisation work within their respective counties.
Local hospitals/Health facilities	The national Fistula Treatment Network is a collection of treatment facilities which are equipped with operating equipment and surgical supplies by ACTION ON FISTULA™. The national Network is an innovative approach that fosters collaboration amongst member hospitals and encourage sharing of resources, improves patient referrals and follow-up care.

Local Context, Equity & Sustainability

15 Local health needs addressed by program

A study commissioned by UNFPA (United Nations Population Fund) estimated 3,000 new cases of obstetric fistula occur annually in Kenya, with approximately one to two fistulas for every 1,000 deliveries. UNFPA estimated that only 7.5 percent of women with fistula are able to access treatment and the backlog of cases was estimated at 30,000. Kenya has existing hospitals, which have spare bed space, but there is an acute need for more trained fistula surgeons to enable them to be filled. Critically, many of the women with fistula live in rural communities and are not aware that help is available or able to afford to reach the hospitals. ACTION ON FISTULA™ was specifically developed to maximise use of existing hospital space by training more surgeons. We are also creating ambassadors to go out into rural areas to identify women in need and pay for their transportation and treatment costs.

THE ACTION ON FISTULA™ website can be found at: <https://www.astellas.com/eu/responsibility/action-on-fistula>

a How needs were assessed

[No response provided]

b Formal needs assessment conducted

[No response provided]

16 Social inequity addressed

Obstetric fistula sufferers are too often subject to severe social stigma due to odour which is constant and humiliating, often driving the patients' family, friends and neighbours away. Stigmatised, these women are also often denied access to education and employment and left to live lives of isolation and poverty. Community outreach and mobilisation is essential to increase awareness of fistula, reduce stigma, and identify and refer women living with fistula to treatment facilities. Very often, women with fistula live in rural and hard-to-reach areas and may suffer stigma and isolation, which diminishes their ability to access to life-transforming care.

Many women and the families and communities in which they live, do not know that fistula is a treatable condition and therefore do not seek out assistance unless they are sensitised and supported by good community outreach programmes. In order to effectively carry out community outreach activities, ACTION ON FISTULA™ works in partnership with local community-based organizations and nongovernmental organizations that are respected and trusted within their communities. The programme tackles stigma by identifying and bringing women in for treatment alongside educating couples, families and entire communities on fistula. In summary, ACTION ON FISTULA™ addresses inequity by providing treatment to poor and marginalized fistula patients, who often live in rural and hard-to-reach communities.

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

ACTION ON FISTULA™ is designed to use the pre-existing infrastructure in Kenya. This means it uses hospitals and units designed to treat women with obstetric fistula. In order to enhance and maximise the infrastructure, we are also training new surgeons with the skills they need to treat more women. This is being done to the highest of standards, according to the International Federation of Gynaecology and Obstetrics (FIGO) guidelines, which are best-in-class and, we believe, ensure that high professional standards are upheld. A senior FIGO representative is also on the Board of the Fistula Foundation.

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

[No response provided]

Local Context, Equity & Sustainability

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

[No response provided]

23 Sustainability plan

The aim of ACTION ON FISTULA™ is to create a legacy in Kenya that will allow more women to be treated once the programme draws to a close. This is why the programme has invested in the training of surgeons and nurses, alongside the building of the Fistula Treatment Network and awareness-raising programmes. These measures will allow more women to be identified and offered treatment long beyond the end of the programme.

Additional Program Information

24 Additional program information

Now in its second phase, grant funding to date of €2.25 million from Astellas Pharma Europe is being used to transform the lives of 4,500 women in Kenya suffering due to obstetric fistula, increase the number of qualified surgeons by 200% and increase the number of nurses to help identify and treat the condition.

a Potential conflict of interest discussed with government entity

[No response provided]

25 Access Accelerated Initiative participant

Yes

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

Yes

Program Indicators

PROGRAM NAME

ACTION ON FISTULA™

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

INDICATOR TYPE STRATEGY 2014-2018 2014-2019 2017 2018

1	Value of resources	Input	All Program Strategies	---	\$2,250,000	---	---
2	Population exposed to community communication activities	Output	Community Awareness and Linkage to Care	---	1,804,619 people	330,800 people	---
3	Population screened	Output	Health Service Delivery	---	---	---	---
4	Number of people trained	Output	Health Service Strengthening	11 people	30 people	0 people	---
5	Number of patients on treatment	Output	Health Service Delivery	4,436 people	5,789 people	1,015 people	1,272 people
6	Sites in use	Output	Health Service Strengthening	6 sites	7 sites	---	---

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	Company	Astellas Pharma Europe Limited collect related data from various internal data source and aggregate them manually.	One-time event
31 Data processing	Company	Astellas Pharma Europe Limited office will report on the expenditure data related to the program to Astellas headquarters (HQ). Astellas HQ will report on the data to Boston University (BU). The Fistula Foundation takes the lead in compiling expenditure data that are to be shared with Astellas. Astellas can then share the relevant information with BU.	Once per year
32 Data validation		[No response provided.]	

33 Challenges in data collection and steps to address challenges

Data can only be collected manually and will therefore be an approximate number.

INDICATOR	2014-2019	2017	2018	2018
1 Value of resources	\$ 2,250,000	---	---	---

Comments: Year-specific data not available.

2014-2019: funds provided to implementing partner for Action on Fistula. (calculated 1 EURO=1.22 USD).

INDICATOR **Population exposed to community communication activities**

2

STRATEGY COMMUNITY AWARENESS AND LINKAGE TO CARE

ITEM	DESCRIPTION
Definition	Number of population reached through a community awareness campaign
Method of measurement	Counting of participants that attend campaign meetings or reached by media messaged disseminated CALCULATION Number of people or participants in the target audience segment who participated or attended the community awareness campaign recorded in a given period of time
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Fistula Foundation	Fistula Foundation has designed reporting tools to capture different program indicators at different levels. These primary tools are completed by community volunteers during their community activities and are submitted to each overarching outreach organization on a monthly basis. The outreach organizations are then responsible for compiling this data and submitting it to the Fistula Foundation on quarterly basis. The approach depends on the specific outreach at hand. In terms of targeted outreaches in which the participants are facilitated, the attendance lists are signed and are used to populate the number of people reached. However when it comes to the general community outreaches and rallies, different volunteers are assigned to do the head count and the totals are populated to get the number of people reached.	Every three months
31 Data processing	Fistula Foundation	Outreach data is tallied on a quarterly matrix, organized by targets and indicators achieved. The number of patient referrals though outreach organizations are also tracked, which includes the method of referral. This information is used to make programmatic decisions.	Every three months

32 Data validation		Outreach numbers are validated on an ongoing basis. Fistula Foundation's quarterly outreach reporting tool includes both a narrative and a matrix section in which the data is captured. This helps our team to identify discrepancies between the two sections, and seek clarification from the outreach organization if needed. The project also performs random quality data assessment (RQDA) during which the source documents are reviewed against the reported data.	
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33 Challenges in data collection and steps to address challenges

[No response provided]

INDICATOR	2014-2019	2017	2018
2 Population exposed to community communication activities	1,804,619 people	330,800 people	---

Comments: Some year-specific data not available.

Number of reached community members with fistula messages.

2017: Number of reached community members with fistula messages in year 2017.

2014-2019: In Phase 2, 5 local organisations have conducted about 10,007 outreach events, reaching over 1,286,319 people. This brings the overall total to Dec 31, 2019 to 1,804, 619 community members being reached with fistula messages

ITEM	DESCRIPTION
Definition	<p>Number of individuals screened for disease as a result of the screening test or procedure being provided by the program</p> <p>Screening activities could include any screening procedures (mammogram, cholesterol measurement, colonoscopy, etc.) delivered directly to a specified population, by the program. Screening activities are often preventive in nature and aim to look for diseases or conditions prior to symptoms developing</p>
Method of measurement	<p>Counting of people who were screened for disease in the program</p> <p>CALCULATION Sum of the number of people screened</p>
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Implementing partner: Fistula Foundation	The hotline operator screens each potential fistula patient and, if they meet the threshold for referral from the screening tool score, refers the patient to the nearest Action on Fistula treatment center. Fistula Foundation reports to Astellas. Each call to the Action on Fistula hotline is logged.	Every 6 months
31 Data processing	Implementing partner: Fistula Foundation	Action on Fistula goes through the hotline call logs and determines which of the call are related to the program and which are not. The calls that were related to the program are summed to provide the number of patients screened. Fistula Foundation reports to Astellas and Astellas reports the data to Boston University.	Every 6 months
32 Data validation		Each call to the Action on Fistula hotline is logged. The hotline log is reviewed against the patient logs for each Action on Fistula partner hospital each month to confirm whether all the clients referred through the hotline were properly referred and received. This helps to follow-up on those who might have not accessed the services for varying reasons.	

33 Challenges in data collection and steps to address challenges

[No response provided]

INDICATOR	2017	2018	2019
3 Population screened	---	---	---

Comments: N/A

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
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Fistula Foundation	Surgeon training takes place 1-2 times per year. Fistula Foundation collects data from partners about this training before and after each training. Fistula Foundation update a one pager tracking sheet after new surgeon trainings are completed to track the number of surgeons that have participated in training.	Every 6 months
31 Data processing	Fistula Foundation	Fistula Foundation does not process data regarding the surgeon training. In order to be certified, surgeons must meet rigorous standards outlined by the International Federation of Gynecology and Obstetrics (FIGO), which leads on this certification. International Federation of Gynecology and Obstetrics processes information related to surgeon performance and final FIGO certification rating. The lead fistula surgeon trainer, Dr. Hillary Mabeya, collects data from each surgeon training which includes data such as the number of hours in training, number of cases observed, number of cases where the trainee were able to perform on their own, among other things, and this information is shared with Fistula Foundation by FIGO, with a recommendation about the trainee's competence upon completion of the training.	Every 6 months

INDICATOR **Number of people trained**

STRATEGY HEALTH SERVICE STRENGTHENING

4

<p>32 Data validation</p>		<p>As very few surgeons are trained each year - specifically two surgeons are trained in a year - this makes it easy to track and validate the data. The Fistula Foundation takes part in the recruitment process hence knows beforehand the number and names of the trainees. During the training the trainee surgeons fill the daily activity log which is used by the trainer to assess them. At the end of the training lead fistula trainer Dr. Mabeya submits his reports and part of the logs to the Foundation. The Foundation cross checks the names on the logs against the names of the recruited surgeons. The final data is then shared with International Federation of Gynecology and Obstetrics (FIGO).</p>	
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33 Challenges in data collection and steps to address challenges

[No response provided]

INDICATOR	2014-2018	2014-2019	2017	2018	2019
4 Number of people trained	11 people	30 people	0 people	---	---

Comments: Year-specific data not available.

Number of trained and certified doctors to the standard level of competency.

2014-2019: The numbers trained during this period are as follows: Number of trained and certified Kenyan doctors to FIGO competency is 7; Number of trained and certified International doctors to FIGO competency is 4; Nurses trained in fistula management is 19.

INDICATOR **Number of patients on treatment**

STRATEGY HEALTH SERVICE DELIVERY

5

ITEM	DESCRIPTION
Definition	Number of patients that have received treatment through the program
Method of measurement	Counting of people who received treatment through the program CALCULATION Sum of the number of people treated
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Fistula Foundation	Fistula Foundation collects surgery data from its hospital partners each month. Hospitals share the number of surgeries completed and patient treatment logs. Each hospital in the network is required to report the number of patients treated on a monthly basis to the program director. Each hospital also must submit a patient log that keeps patient names confidential but shares in detail their age, length of time spent with fistula, any previous surgeries and final outcome of their program-related fistula surgery. Each of our outreach organization partners also tracks patients they have referred, as well as the method of referrals. This helps the Fistula Foundation team to understand the number of patients referred through outreach organizations and the number of self-referred clients.	Every month
31 Data processing	Fistula Foundation	The surgery data Fistula Foundation collect is tallied in a spreadsheet, which tracks the number of surgeries completed per facility, per month and per year.	Every month
32 Data validation		Patients treated are validated by cross-reference with patient logs, which are provided by each hospital.	

33 Challenges in data collection and steps to address challenges

[No response provided]

INDICATOR	2014-2018	2014-2019	2017	2018	2019
5 Number of patients on treatment	4,436 people	5,789 people	1,015 people	1,272 people	---

Comments: Some year-specific data not available. Number of patients successfully treated with reconstructive surgery. 2014-2018: 3,257 surgeries performed during Phase 2, which means we have now surpassed our Phase 2 target to support life-transforming corrective surgery for 2,000 women with obstetric fistula. A total of 5,789 fistula surgeries have been supported since the program's inception. The annual number of surgeries carried out can be summarised as follows: In 2014-15 there were 199 surgeries; in 2015-16 there were 660 surgeries; in 2016-17 there were 1281 surgeries; in 2017-18 there were 1004 surgeries; in 2018-19 there were 1258 surgeries and in 2019-20 there were 1387 surgeries.

ITEM	DESCRIPTION
Definition	Number of facilities where the services are offered
Method of measurement	The number of facilities or infrastructure units which are in use and where services are offered CALCULATION Sum of the numerical count of facilities or infrastructure units where services are offered
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Fistula Foundation	Fistula Foundation updates Astellas as and when a new treatment provider joins the Action on Fistula Treatment Network.	Ongoing
31 Data processing	Fistula Foundation	Fistula Foundation reports new facilities to Astellas verbally and in its reports every 6 months. New treatment centers are required to report to the Fistula Foundation on their activities monthly, as the other existing facilities do.	Ongoing
32 Data validation		[No response provided.]	

33 Challenges in data collection and steps to address challenges

[No response provided].

INDICATOR	2014-2018	2014-2019	2017	2018	2019
6 Sites in use	6 sites	7 sites	---	---	---

Comments: Year-specific data not available. Number of Centers in the Fistula Treatment Network.

2014-2019: Increasing access to timely, quality treatment and care for women with fistula is key to eradicating fistula. In the period under review, the project continues to treat women with fistula through 7 designated facilities in the treatment network with Narok County Referral Hospital being the latest entry in the treatment network. The others are at: Gynocare Fistula Center, Eldoret Jamaa Mission Hospital, Nairobi Cherangany Nursing Home, Kitale Kisumu East District Hospital Bomu Hospital, Mombasa Kisii Gynocare Center The usage of sites from inception of the programme can be shown as follows: in 2014-15 there were 4 sites; in 2015-16 there were 5 sites; in 2016-17 there were 6 sites; in 2017-18 there were 6 sites; in 2018-19 there were 6 sites and in 2019-20 there are 7 sites.

Program Documents

Program Documents

1. Data for surgey counts; 2014-2020. Available at: https://bit.ly/actiononfistula_surgeries
2. Waweru-Wanyama, M. Fistula in Kenya: The Facts and Needed Approcahes. 2014. Available at: <https://bit.ly/fistulakenya>

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 is 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.

Company-submitted Situation Analysis

1. Waweru-Wanyama, M. Fistula in Kenya: The Facts and Needed Approcahes. 2014.

Available at: <https://bit.ly/fistulakenya>

