

INTEGRATED WITH 'MULTINATIONAL LUNG CANCER CONTROL PROGRAMME' IN 2020

Secure The Future Kwa-Zulu Natal South Africa

Bristol-Myers Squibb Foundation

Submitted as part of Access Accelerated

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Program Description

Program Overview

1 Program Name

Secure The Future - KwaZulu Natal
South Africa

2 Diseases program aims to address

- Cancer (General; Lung)

3 Beneficiary population

- General Population

4 Countries

- South Africa

5 Program start date

June 01, 2017

6 Anticipated program completion date

May 31, 2020

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8 Program summary

Globally, there are approximately 1.8 million new cases of lung cancer per year. Lung Cancer accounts for the highest rates of cancer-related mortality globally. Despite this, many African countries lack information regarding the epidemiology of lung cancer and its control. There is also the compounding heavy burden of comorbidities in Sub-Saharan Africa, including Human Immunodeficiency Virus (HIV) and Tuberculosis (TB). This is the first proposal of a collaboration between 4 African countries on lung cancer across the continent. We propose to develop a lung cancer control program in the specified regions of the four participating countries with emphasis on improvement of access to early diagnostics and addressing the barriers to optimal outcomes.

Secure the Future - Lung Cancer is being implemented in multiple countries but this description will be confined to South Africa. Separate programs in Kenya, Swaziland and Tanzania are separately described in the Access observatory. Although the programs are related, there are differences such as different partners, thus the need for separate descriptions.

The project in South Africa will cover the following four sub-projects:

Project 1: Raising awareness on lung cancer in the communities of KwaZulu-Natal, South Africa and evaluating the impact of oncological services on cancer among the three hospitals in KwaZulu-Natal.

Project 2: Conducting a needs assessment in order to identify facilitators and barriers to lung cancer patient access, referral, diagnosis and treatment in the study settings.

Project 3: Assessing the risk factors associated with lung cancer in the study settings.

Project 4: Assessing the factors determining progressive utilization of palliative care services by patients with cancer (at public and private sectors).

Program Overview

8 Program summary cont.

Contextual introduction:

This is a multinational study covering four countries in sub-Saharan Africa. However, this proposal is mainly focused on the KwaZulu-Natal study sites in South Africa, in line with the federal system arrangement as proposed by the funder: Bristol-Myers Squibb Foundation (BMSF). Therefore, information pertaining to the other three (Kenya, Swaziland and Tanzania) participating countries may not be of sufficient detail.

Proposed program:

a. Goal:

The goal of the MLCCP is to improve access to early diagnostic services for lung cancer by addressing the barriers of cancer care through working with communities and the Ministries of Health in the identified regions in the four countries with a potential for scale-up.

b. Justification:

Lung cancer is the most common cancer worldwide, and disproportionately affects developing countries where over 58% of cases occur. This however is in sharp contrast with low incidence rates of lung cancers reported in Africa (7.7 per 100,000 in men and 2.6 per 100,000 in women, respectively).¹ This apparently low burden of lung cancers in the context of critical lack of accurate data likely reflects enormous underestimations of the true burden, considering the high prevalence in the African setting of some major risk factors for lung cancer, such as pulmonary tuberculosis and HIV infection. Indeed, most African countries lack nationwide or regional population-based cancer registries, and have no reliable source of mortality data.^{1,3} The epidemiology of lung cancer is largely unknown in Africa, reflecting until recently, the low priority given to cancer and non-communicable diseases (NCDs) research in this setting.

In most African settings, there is low cancer awareness, uncoordinated or absent screening services, late cancer diagnoses, when therapeutic solutions, where available, are less likely to be effective.⁴ In addition, cultural beliefs in these settings influence health seeking behavior, with patients with warning signs and those with clinical signs suggestive of cancer or diagnosed with cancer resorting to alternative medicine either preferentially, or in parallel with modern medicine.⁴ For example, the number of lung cancer cases reported from 2 of the collaborating centers (Eldoret in Kenya and Mwanza in Tanzania), over the preceding period was extremely small, for Eldoret-Kenya only 53 cases 2011-2014 and for Mwanza 69 cases over 5 years. All these factors have contributed to lack of a true burden estimation in this region, which this program will address.

c. Project Scope:

The project will span three years and will involve a mix of interventions and evaluations (2 years for South Africa). The overall methodological approach is one of pragmatic studies. Pragmatic studies, as opposed to explanatory trials, seek to answer a research question in the context of usual clinical practice, without requiring extraordinary additional changes. They have the advantages of being easier to conduct in real-world conditions, and they apply the research question to generalized populations as opposed to explanatory trials, where the intervention is applied in optimal conditions, to highly selected and controlled population.^{5,6}

The scope of the overall multinational project covers the following:

1. Assessing the readiness of the health system to prevent and control lung cancers.
2. Identify pathways of care of lung cancer.
3. Identify the enablers to achieving earlier diagnosis.
4. Strengthen hospital-based cancer surveillance/registries.

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Community Awareness and Linkage to Care

| ACTIVITY | DESCRIPTION |
|----------------|--|
| Communication | Awareness campaign materials to the community. Create and disseminate lung cancer awareness brochures and material. |
| Infrastructure | Provide vehicles to enable distribution of lung cancer awareness materials. |

Strategy 2: Health Service Strengthening

| ACTIVITY | DESCRIPTION |
|----------------|---|
| Planning | Meetings with local institutions to assess main access barriers and identify risk factors. |
| Training | <p>Training programs for local healthcare workers to standardized and improve cancer quality of care.</p> <p>Train cancer registry staff to properly document cases</p> <p>Train administrators and researchers on bio-banking's importance in research and care</p> <p>Establish a biobank for storage of the lung pathology specimen for potential translational research</p> <p>Creation and validation of risk-factor screening tools for lung cancer.</p> <p>Establish tele-pathology with the participating centers for pathology reviews.</p> <p>Training programs for local healthcare workers to standardized and improve cancer quality of care.</p> <p>Train cancer registry staff to properly document cases</p> <p>Train administrators and researchers on bio-banking's importance in research and care</p> |
| Infrastructure | Establish a biobank for storage of the lung pathology specimen for potential translational research. |
| Technology | <p>Creation and validation of risk-factor screening tools for lung cancer.</p> <p>Establish tele-pathology with the participating centers for pathology reviews.</p> |
| Management | Creation/establishment of boards for assessment of lung cancer cases. |

10 Strategy by country

| STRATEGY | COUNTRY |
|---|--------------|
| Community Awareness and Linkage to Care | South Africa |
| Health Service Strengthening | South Africa |

Companies, Partners & Stakeholders

11 Company roles

| COMPANY | ROLE |
|----------------------|---------------------|
| Bristol-Myers Squibb | Funder and sponsor. |

12 Funding and implementing partners

| PARTNER | ROLE/URL | SECTOR |
|---|--|-----------|
| Bristol-Myers Squibb Foundation | Sponsor and funder. https://www.bms.com/about-us/responsibility/bristol-myers-squibb-foundation.html | Private |
| World Health Organization (WHO) | Provided technical support in establishing cancer registries to include lung cancer. http://www.who.int/en/ | Public |
| Addington Hospital | Some of the roles of the university of KwaZulu-Natal and participating health facilities include: (1) Coordinating and managing the project, (2) Validating the tool for lung cancer screening of high-risk groups for lung cancer (TB, HIV, Smokers, etc.), including the pilot of the tool. (3) Developing a data management strategy to document all the cancer patients enrolled into the program and their demographics, as well as the reasons for delays in diagnosis and care throughout the continuum of lung cancer care. (4) Developing cancer awareness materials and implementing the awareness program. (5) Establishing support groups within the communities. (6) Understanding Pathways of care in KZN. (7) Training – Palliative care home based care http://www.kznhealth.gov.za/addingtonhospital.htm | Public |
| African Cancer Registry Network (AFCRN) | Deliver tailored training in population-based cancer registration and use of data. http://afcrn.org/ | Voluntary |
| Bugando Medical Centre | Bugando Medical Centre in Mwanza is a partner involved in: (1) validating the tool for lung cancer screening of high-risk groups for lung cancer (TB, HIV, Smokers, etc.), including the pilot of the tool; (2) Developing a data management strategy to document all the cancer patients enrolled into the program and their demographics, as well as the reasons for delays in diagnosis and care throughout the continuum of lung cancer care.(3) Developing standardized synoptic pathology reporting, diagnostic algorithms and treatment protocols for lung cancer (4) Treatment Protocol development(5) Local SoPs for Specimens Storage. (6) Training http://www.bugandomedicalcentre.go.tz/ | Private |

Companies, Partners & Stakeholders

12 Funding and implementing partners, cont.

| | | |
|---|--|-----------|
| Catholic University of Health and Allied Sciences | Catholic University of Health and Allied Sciences is a partner that supports Bugando Medical Centre to establish and test infrastructure for ongoing monitoring of lung cancer screening, detection, treatment and outcomes, in order to inform ongoing improvement in cancer related prevention, health systems and policy solutions. https://www.bugando.ac.tz/ | Voluntary |
| Greys Hospital | Some of the roles of the university of KwaZulu-Natal and participating health facilities include: (1) Coordinating and managing the project, (2) Validating the tool for lung cancer screening of high-risk groups for lung cancer (TB, HIV, Smokers, etc.), including the pilot of the tool. (3) Developing a data management strategy to document all the cancer patients enrolled into the program and their demographics, as well as the reasons for delays in diagnosis and care throughout the continuum of lung cancer care. (4) Developing cancer awareness materials and implementing the awareness program. (5) Establishing support groups within the communities. (6) Understanding Pathways of care in KZN. (7) Training –Palliative care home based care. http://www.kznhealth.gov.za/greyshospital.htm | Public |
| Inkosi Albert Luthuli Central Hospital | Some of the roles of the University of KwaZulu-Natal and participating health facilities (noted below in collaboration) include: (1) Coordinating and managing the project, (2) Validating the tool for lung cancer screening of high-risk groups for lung cancer (TB, HIV, Smokers, etc.), including the pilot of the tool. (3) Developing a data management strategy to document all the cancer patients enrolled into the program and their demographics, as well as the reasons for delays in diagnosis and care throughout the continuum of lung cancer care. (4) Developing cancer awareness materials and implementing the awareness program. (5) Establishing support groups within the communities. (6) Understanding Pathways of care in KZN. (7) Training –Palliative care home based care. http://www.kznhealth.gov.za/ | Public |
| KwaZulu-Natal Department of Health | Some of the roles of the university of KwaZulu-Natal and participating health facilities include: (1) Coordinating and managing the project, (2) Validating the tool for lung cancer screening of high-risk groups for lung cancer (TB, HIV, Smokers, etc.), including the pilot of the tool. (3) Developing a data management strategy to document all the cancer patients enrolled into the program and their demographics, as well as the reasons for delays in diagnosis and care throughout the continuum of lung cancer care. (4) Developing cancer awareness materials and implementing the awareness program. (5) Establishing support groups within the communities. (6) Understanding Pathways of care in KZN. (7) Training –Palliative care home based care. http://www.kznhealth.gov.za/ | Public |

Companies, Partners & Stakeholders

13 Funding and implementing partners by country

| PARTNER | COUNTRY |
|---|--------------|
| Bristol-Myers Squibb Foundation | South Africa |
| World Health Organization (WHO) | South Africa |
| Addington Hospital | South Africa |
| African Cancer Registry Network (AFCRN) | South Africa |
| Bugando Medical Centre | South Africa |
| Catholic University of Health and Allied Sciences | South Africa |
| Greys Hospital | South Africa |
| Inkosi Albert Luthuli Central Hospital | South Africa |
| KwaZulu-Natal Department of Health | South Africa |

14 Stakeholders

| STAKEHOLDER | DESCRIPTION OF ENGAGEMENT |
|-------------------------------------|---|
| Government | <p>Ministry of Health is a partner involved in improving access to early diagnostic services for lung cancer by addressing the barriers of cancer care.</p> <p>WHO is a partner providing technical support in establishing cancer registries to include lung cancer.</p> |
| Local Universities | Catholic University of Health and Allied Sciences is a partner that supports Bugando Medical Centre to establish and test infrastructure for ongoing monitoring of lung cancer screening, detection, treatment and outcomes, in order to inform ongoing improvement in cancer related prevention, health systems and policy solutions. |
| Local Hospitals / Health Facilities | <p>Bugando Medical Centre in Mwanza is a partner involved in:</p> <ol style="list-style-type: none"> 1. Validating the tool for lung cancer screening of high-risk groups for lung cancer (TB, HIV, Smokers, etc.), including the pilot of the tool. 2. Developing a data management strategy to document all the cancer patients enrolled into the program and their demographics, as well as the reasons for delays in diagnosis and care throughout the continuum of lung cancer care. 3. Developing standardized synoptic pathology reporting, diagnostic algorithms and treatment protocols for lung cancer 4. Treatment Protocol development. 5. Local SoPs for Specimens Storage. 6. Training. |

Local Context, Equity & Sustainability

15 Local health needs addressed by program

Collaboration, involvement and participatory approaches have been the key to our Program. The KZN Non-communicable Diseases Directorate, Research directorate, and CEOs of the health facilities are in support of the Program.

South Africa's (SA) health system consists of a large public sector, a smaller but fast growing private sector and an NGO sector. The public health sector is funded by the state. The high levels of poverty and unemployment in the country mean that healthcare remains largely the burden of the state with the National Department of Health holding overall responsibility for health care, with a specific responsibility for the public sector. Although there are high expenditures, health outcomes are relatively poor in comparison with other similar middle-income countries, reflecting an inequity in healthcare in the country.⁷

Situational Analysis of Cancer in SA as from 2011:

Cancer has been a notifiable disease in South Africa and the South African Cancer Registry (NCR) is the mandated national institution to collect information. The legislation makes provision for population based cancer registries at a local level and that makes a KwaZulu-Natal or Durban cancer registry a possibility.

According to the NCR, a pathology-based cancer registry, the most common cancers (shown in Table 1) among men currently are prostate cancer, lung cancer and colorectal cancer. The most common cancer in women in South Africa is breast cancer followed by cervical cancer and colorectal cancer, with lung cancer being the 7th most prevalent cancer.⁸ These are underestimations of cancer prevalence because the pathology based registry only reports laboratory confirmed cases and is not as extensive as a population based cancer registry.

Table: Top Common Cancers in South African among Men and Women by number of cases and life-time risk in 2013

| TYPE OF CANCER | WOMEN | | | MEN | | |
|----------------|------------------|--------------------|---------------------------|------------------|--------------------|---------------------------|
| | NO OF CASES 2013 | LIFETIME RISK 2013 | % COMPARED TO ALL CANCERS | NO OF CASES 2013 | LIFETIME RISK 2013 | % COMPARED TO ALL CANCERS |
| BREAST | 8131 | 1:28 | 22.22 | - | - | - |
| CERVIX | 5701 | 1:44 | 15.58 | - | - | - |
| COLORECTAL | 1542 | 0.142361111 | 4.21 | 1906 | 0.09375 | 5.3 |
| UTERUS | 1152 | 0.152083333 | 3.15 | - | - | - |
| LUNG | 923 | 0.184027778 | 2.52 | 1766 | 0.094444 | 4.91 |
| OESOPHAGUS | 651 | 0.263194444 | 1.78 | 844 | 0.157639 | 2.35 |
| PROSTATE | - | - | - | 6778 | 1:18 | 18.86 |
| BLADDER | 307 | 0.534027778 | 0.84 | 952 | 0.14375 | 2.65 |
| MELANOMA | 723 | 0.284027778 | 1.98 | 819 | 0.16875 | 2.28 |
| All cancers | 36595 | 1:09 | | 35935 | 1:06 | - |

Source: South African National Cancer Registry. Cancer in South Africa, 2013 - Johannesburg. www.ncr.ac.za. Accessed 19 October 2017

Local Context, Equity & Sustainability

15 Local health needs addressed by program, cont.

A comprehensive National Health and Nutrition survey found that 20.8% of the population reported a history of having smoked tobacco¹² and 17.7% reported being exposed to environmental tobacco smoke (ETS) at home on a daily basis. According to SANHANES-1, ETS is significantly higher for males (20.4%) than females (15.4%). Introduction of strong tobacco control policies as well as interventions, such as health education programmes led to the decline in smoking prevalence among school children from 23.0% in 1999 to 16.9% in 2011. Smoking prevalence among men declined from 40% in 1995 to 22% in 2010, but remained unchanged among women at 9%.

A study investigating the feasibility of a population based cancer registry in Durban identified Addington Hospital as the only institution that had instituted a hospital based cancer registry. No other institution in the Durban was doing cancer surveillance although Inkosi Albert Luthuli Central Hospital (IALCH) houses the main public laboratory that diagnoses cancer in the province.

a How needs were assessed
[No response provided]

b Formal needs assessment conducted
[No response provided]

16 Social inequity addressed

Through this program, continuous quality improvement in cancer related prevention, health systems and policy solutions will allow to ease the health inequity gap in lung cancer diagnosis and treatment between South Africa and high income countries, for example. This will be achieved by establishing and testing infrastructure for ongoing monitoring of lung cancer screening, detection, treatment and outcomes. Knowing the real or close to real magnitude of lung cancer in the country will attract proper planning for early detection with treatment aims which has a curative intention rather than palliation, this program will enable treatment for all irrespective of the locality or economic status of the patient as all will be treated equally through projections driven by the project.

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

By partnering with local hospitals and universities, as well as the Ministry of Health of South Africa –KZN department, this program has been designed considering the existence of local resources. Local practice and policies are actively included in design and implementation through surveys, active participation of local professionals, trainings preparations, creation of awareness resources, or other materials.

In addition, this project will build capacity: As the mandate of the University and the project funder, which is to build a research ethos that acknowledges the responsibility of academic staff to nurture its postgraduate students, and to be a pre-eminent producer of new knowledge that is both local and global in context, this project plans to enroll a total of nine students, namely eight Master of Medical Science (MMedSc) and one Doctor of Philosophy (PhD). These students will actively participate in conducting their research work under the banner of these four sub-projects. This is in keeping with the ethos of nurturing postgraduate students and promoting the development of intellectual capital in the African region.

Furthermore, it is the mandate of the university and the funder to promote community engagement and empowerment. Our project will be community based and empowering five communities (two in PMB and three in Durban) with knowledge on lung cancer and training palliative care health providers.

Local Context, Equity & Sustainability

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

No further information at this time.

- 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

Secure the Future Tanzania has engaged with a local university and medical center to develop a standardized pathology reporting, diagnostic algorithms and treatment protocols for lung cancer which will continue to be used long after the program has ended. The program is also helping to establish and strengthen cancer registries in which will continue to be in use after the program ends.

Through this project the referral mechanism from the rural areas to the Medical centre and back will be strengthened, this will in turn ensure the continuation of the process not only for lung cancer but even for other malignancies. Lastly by involving the department of NCD under the ministry of health a coordination of the activities will be ensured.

Additional Program Information

24 Additional program information

No other information at this time.

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.

Resources

1. Ferlay et al., 2015. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. *Int J Cancer*. 136(5):E359-86. doi: 10.1002/ijc.29210. Epub 2014 Oct 9.
2. Siegel, K., Naishadham, D., and Jemal, A. (2012). Cancer statistics, 2012. *CA: A Cancer Journal for Clinicians*, 62 (1), 10-29.
3. Joubert, J., Rao, C., Bradshaw, D., Dorrington, R. E., Vos, T., & Lopez, A. D. (2012). Characteristics, availability and uses of vital registration and other mortality data sources in post-democracy South Africa. *Global Health Action*, 5, 10.3402/gha.v5i0.19263. <http://doi.org/10.3402/gha.v5i0.19263>
4. Nanguzgambo, A. B., Razack, R., Louw, M., Bolliger, C. T. (2011). Immunochemistry and lung cancer: Application in diagnosis, prognosis and targeted therapy. *Oncology*, 80, 247-256
5. Ford, I., & Norrie, J. (2016). Pragmatic Trials. *New England Journal of Medicine*. 375, 454-463. DOI: 10.1056/NEJMr1510059
6. Patsopoulos, N. A. (2011). A pragmatic view on pragmatic trials. *Dialogues in Clinical Neuroscience*, 13(2), 217–224.
7. Jobson M. 2015. Structure of the health systems in SA, Khulumani Support Group, Johannesburg.
8. WHO. International Agency for Research on Cancer. Retrieved from <http://www.iarc.fr/en/publications/pdfs-online/index.php>
9. The South African Nutritional and Health Examination Survey (SANHANES-1)

Program Indicators

Not yet available for this program

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 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

- Responsible party: For this indicator, please indicate the party/parties responsible for data collection.
- Data collection — Description: Please briefly describe the data source and collection procedure in detail.
- Data collection — Frequency: For this indicator, please indicate the frequency of data collection.

31 Data processing

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

