General instructions

Thanks for your support and collaboration to CanScreen5 project. To explain each query in a clear, precise and unambiguous manner, a guide was designed (pages 3-9). After reading the guide, if you still require assistance in filling any of the form, please contact us by email at canscreen5@iarc.fr

1.	**General information**	
1.1	Country:_____	
1.2	Reporting for: *(1. national; 2. sub-national)*	[ ]
1.3	Name of the geographic area(s) if not reporting for entire country:_____ _____	
1.4	Index year (use current year unless you are reporting from a published report):	[ ] [ ] [ ] [ ]
1.5	Source: *(1. directly from programme (managed by Health Ministry/Health Authority); 2. official report (published by programme or Health Ministry/Health Authority); 3. peer-reviewed publication; 4. other reports (published by NGO/academic institutions); 5. other_____)* *(Please provide link (if applicable) or email the document to canscreen5@iarc.fr):* _____	[ ]
2.	**Organization of screening**	
2.1	Is there an individual/team/institution responsible for management/coordination of the cancer screening activities? *(1. yes; 2. no; 3. unknown)*	[ ]
2.1.1	If yes, please provide name of team/institution or the designation of the individual:_____	
2.2	Does the Health Ministry/Health Authority allocate a budget to cancer screening? *(1. yes; 2. no; 3. unknown)*	[ ]
2.3	Is there a policy document from the Health Ministry/Health Authority that recommends cancer screening? *(1. yes; 2. no; 3. unknown)*	[ ]
2.3.1	If yes, how is the policy documented? *(1. law; 2. notification (from Health Ministry/Health Authority); 3. recommendation (from public institution/professional organization/association and endorsed by the Health Ministry/Health Authority))* *(Please provide link (if available) or email the document to canscreen5@iarc.fr):* _____	[ ]
2.4	Year screening programme was initiated: *(9999. if no programme; 0000. if unknown)*	[ ] [ ] [ ] [ ]
2.5	Was a pilot implemented before introduction of the screening programme or is a pilot ongoing? *(1. yes; 2. no; 3. unknown)*	[ ]
2.5.1	If yes, has the pilot programme been evaluated? *(1. pilot ongoing; 2.evaluated and report published; 3. evaluated but no report published; 4. not evaluated; 5. unknown)*	[ ]
2.6	Are the screening tests available free of charge to the eligible population? *(1. yes; 2. no; 3. unknown)*	[ ]
2.6.1	If the screening tests are not free, is the cost reimbursed from any source? *(1. yes, fully reimbursed; 2. yes, partially; 3. no; 4. unknown)*	[ ]
2.7	Are the diagnostic tests available free of charge to the screen-positive individuals? *(1. yes; 2. no or partially; 3. unknown)*	[ ]
2.8	Are treatment services available free of charge to individuals with a diagnosis of cancer? *(1. yes; 2. no or partially; 3. unknown)*	[ ]
2.9	Any other information related to screening organization:_____	
3.	**Information system and data collection**	
3.1	Is there a computerized information system that collects screening-related data on **individual** basis? *(1. yes; 2. no; 3. unknown)*	[ ]
3.1.1	If yes, for which purpose? *(1. identify and invite eligible population; 2. collect screening participation; 3. collect screening test results; 4. collect info on diagnosis; 5. collect info on stage; 6. collect info on treatment)*	[ ].[ ].[ ].[ ].[ ].[ ] *(multiple responses)*
3.1.2	If yes, at which level does this computerized information system exist? *(1. national; 2. sub-national; 3. both national and sub-national; 4.unknown)*	[ ]
3.2	Is there a system (computerized or paper-based) that gathers **aggregated** data on screening activities? *(1. yes; 2. no; 3. unknown)*	[ ]
3.2.1	If yes, for which purpose? *(1. report number screened; 2. report number of screen positive; 3. report number further assessed; 4. report number treated)*	[ ].[ ].[ ].[ ] *(multiple responses)*
3.2.2	If yes, at which level does this computerized or paper-based information system exist? *(1. national; 2. sub-national; 3. both national and sub-national; 4.unknown)*	[ ]
3.3	Is there a system to collect information on screening outside the programme (opportunistic screening/private sector)? *(1. yes; 2. no; 3. cannot differentiate; 4. unknown)*	[ ]
3.4	Are screening data linked with population-based cancer registries (PBCR)? *(1. yes; 2. PBCR exists but is not linked; 3. no PBCR; 4. unknown)*	[ ]
3.5	Any other information related to information system (e.g. quality control of data collection, etc.):_____ _____	

4.	**Screening protocol**	
4.1	Is there a screening protocol or guideline? *(1. yes; 2. no; 3. unknown) (If yes, please provide link (if available) or email the document to canscreen5@iarc.fr):* _____	[ ]
4.2	If yes, year when the current protocol was developed/last updated: [ ] [ ] [ ] [ ]- YYYY *9999 if no documented protocol; 0000 if unknown*	
4.3	If yes, please provide information on the screening protocol (list of screening tests provided below)	
4.3.1	Primary screening test [ ] Target age ([ ] [ ]- [ ] [ ]) Screening interval ([ ] [ ] months)	
4.3.2	Primary screening test [ ] Target age ([ ] [ ]- [ ] [ ]) Screening interval ([ ] [ ] months)	
4.3.3	Primary screening test [ ] Target age ([ ] [ ]- [ ] [ ]) Screening interval ([ ] [ ] months)	
4.3.4	Primary screening test [ ] Target age ([ ] [ ]- [ ] [ ]) Screening interval ([ ] [ ] months)	
	Primary screening tests*: 1. mammography (Mx) or digital breast tomosynthesis (DBT); 2. (Mx or DBT) + (clinical breast examination (CBE) or ultrasound (US)); 3. CBE + US; 4. US; 5. CBE*	
4.4	If yes, are all mammograms read by two radiologists independently? *(1. yes, all mammograms; 2. yes, negative mammograms only; 3. no; 4. unknown)*	[ ]
4.5	Any other information related to screening protocol (e.g. a different screening protocol not based on age, but for selected population, etc.): _____	
5.	**Invitations for screening and further assessment**	
5.1	Are there any initiatives to create population awareness by the Health Ministry/Health Authority? *(1. yes; 2. no; 3. unknown)*	[ ]
5.1.1	If yes, what are the approaches: *(1. mass media campaign; 2. small media campaign; 3. group education; 4. one-on-one education; 5. other_____; 6. unknown)*	[ ].[ ].[ ].[ ].[ ] *(multiple responses)*
5.2	Is there a system to send individual invitations to all the eligible population? *(1. yes; 2. no; 3. unknown)*	[ ]
5.2.1	If yes, from which source are the eligible individuals identified? *(1. population register; 2. electoral roll; 3. list form GP or PHC; 4. list of an insurance company; 5. other_____; 6. unknown)*	[ ].[ ].[ ].[ ].[ ] *(multiple responses)*
5.2.2	If yes, what is the method of inviting the eligible individuals? *(1. letter; 2. email; 3. SMS; 4. phone calls; 5. home visits by health workers; 6. other _____; 7. unknown)*	[ ].[ ].[ ].[ ].[ ] *(multiple responses)*
5.3	Is there a system to invite selected populations only? *(1. not screened in the round; 2. high risk populations only (criteria for high risk: _____); 3. other: _____; 4. none; 5. unknown)*	[ ].[ ].[ ] *(multiple responses)*
5.4	Are the screen-positive individuals actively contacted to ensure compliance with further assessment? *(1. yes, systematically; 2. no or sporadically; 3. unknown)*	[ ]
5.5	Are the individuals with a cancer diagnosis actively contacted to ensure compliance with further management? *(1. yes, systematically; 2. no or sporadically; 3. unknown)*	[ ]
5.6	Does the programme collect data on the stage of the cancers detected through the programme? *(1. yes, systematically; 2. no or sporadically; 3. unknown)*	[ ]
5.7	Does the programme collect data on the treatment of the cancers detected through the programme? *(1. yes, systematically; 2. no or sporadically; 3. unknown)*	[ ]
5.8	Any other information related to invitation and further assessment (e.g. invitation system excludes cancer cases, etc.): _____	
6.	**Quality Assurance (QA) of screening activities**	
6.1	Is there a documented guideline/policy for quality assurance of the screening service delivery? *(1. yes; 2. no; 3. unknown) (If yes, please provide link (if available) or email the document to canscreen5@iarc.fr):* _____ _____	[ ]
6.2	Is there an individual/team/institution responsible for quality assurance of the screening service delivery? *(1. yes; 2. no; 3. unknown)*	[ ]
6.2.1	If yes, please provide name of team/institution or the designation of the individual: _____	
6.3	Is there a system of accreditation of mammography units? *(1. yes; 2. no; 3. unknown)*	[ ]
6.4	Is there a system of accreditation for pathology services? *(1. yes; 2. no; 3. unknown)*	[ ]
6.5	Are there specified performance indicators to assess the performance of screening? *(1. yes; 2. no; 3. unknown)*	[ ]
6.5.1	If yes, are the reference standards defined for the indicators? *(1. yes; 2. no; 3. unknown)*	[ ]
6.6	Were the performance reports of screening programme published in the last five years? *(1. yes; 2. no; 3. unknown) (If yes, please provide link (if available) or email the document to canscreen5@iarc.fr):* _____ _____	[ ]
6.7	Any other information related to quality assurance (e.g. the key performance indicators and their standards, etc.): _____	

General instructions

Thanks for your support and collaboration to CanScreen5 project. The guide is designed to facilitate collection and submission of information/data for CanScreen5 project using the standardized data collection tools. The guide aims to explain each query in a clear, precise and unambiguous manner so that they are interpreted in the same way by everyone collecting and providing data as well as by those studying and interpreting the results. After reading this document, if you still require assistance in filling any of the data forms, please contact us by email at canscreen5@iarc.fr

Terms in bold and underlined have a definition in Appendix I (pages 7-9).

1. General information

For this part, you will provide general information for breast cancer screening you are reporting for, including country, index year, data source, etc.

1.1 Please indicate the country, which the following report refers to.

1.2 If you report for the national level, you will report for the entire country. If you report for the **sub-national** level, you need to indicate the specific geographic area under consideration (1.3).

1.3 Please indicate all the specific geographic areas if you are reporting at sub-national level.

1.4 If you are reporting current data directly from programme managed by Health Ministry/Health Authority, please indicate the current year. If you are extracting data from a report published earlier, please indicate the corresponding year of data collection from most recent published reports/peer-reviewed publications. All of the items below should correspond to this index year.

1.5 Please select "directly from programme", if you are involved in implementing, supervising or reviewing the screening activities on behalf of or in collaboration with the Ministry of Health or other Health Authorities. For other options, if the information is available in any published report/guideline document, including the official report published by programme or Health Ministry/Health Authority, peer-reviewed publication, and other reports published by NGO/academic institutions, please provide the link (if available) or email the electronic document to canscreen5@iarc.fr

Please note that all documents provided on a voluntary basis would also be most encouraged. The core objective of the requested document, link for download or electronic document, is for the quality assurance of the CanScreen5 project. Please rest assured all documents will not be shared or available for public use.

2. Organization of screening

For this section, you will provide the overview of cancer screening organization (including who is responsible for implementation, public funding, an explicit policy, etc.).

2.1 In the country/region you are reporting for, is there specific individual/team/institution/ responsible for management/coordination of cancer screening activities? If no, please go to Question 2.2 directly.

2.1.1 If yes**,** please indicate the specific team/institution responsible for the cancer screening activities. For individual, please indicate his/her job position.

2.2 Is specific funding from Health Ministry/Health Authority allocated to the cancer screening activities? The response will be 'yes' even if the budget for screening is part of the overall budget for cancer control or NCD control programme.

2.3 Is there a **screening policy** document recommending breast cancer screening? Such a document is issued by the Health Ministry/Health Authority specifying their commitment to provide cancer screening to the target population. If no, please go to Question 2.4 directly.

2.3.1 If yes, please indicate if the policy document is in the form of a legislation or an official notification from the Ministry/Authority. The notification/decree from the Health Ministry/Health Authority should be published in the government official publication (official journal, official gazette, official newspaper, official bulletin, etc.). Sometimes the recommendations (e.g. screening guidelines) could be developed by a public institution (including National

Cancer Institute)/professional organization/association and endorsed by the Health Ministry/Health Authority. Please provide the link (if available) or email the electronic document to canscreen5@iarc.fr

2.4 Please indicate the specific year when the **screening programme** was initiated. If no cancer screening programme, please indicate 9999. Please indicate 0000 if the initiation year is unknown.

2.5 Before the cancer screening implementation across the country/region, was a **pilot programme** implemented previously or is the pilot ongoing recently? If no, please go to Question 2.6 directly.

2.5.1 If yes, please indicate the status of the evaluation of the pilot programme. Ideally, a pilot programme should be evaluated and the report should be published before scaling up the programme. Respond "pilot ongoing", if the pilot is ongoing recently. Respond "evaluated and report published", if the pilot programme has been evaluated and the report has been published.

2.6 For the eligible population for cancer screening, is the screening test administered **free of charge**, meaning no immediate payment by the individual for availing the screening services? If yes, please go to Question 2.7 directly.

2.6.1 If no, is the cost reimbursed from government/local government, health insurance company or any other sources, fully or partially?

2.7 For screen-positive individuals needing **further assessment**, are the diagnosis tests available **free of charge**, meaning no immediate payment by the individual for availing the diagnostic services?

2.8 For individuals with diagnosis of breast cancer, are the treatment services available **free of charge**, meaning no immediate payment by the individual for availing the treatment services?

2.9 If there is other information related to screening organization, please indicate here.

3. Information system and data collection

In this section, please provide information on cancer screening information system and data collection.

3.1 Is there a computerized information system to collect data related to some or all services related to screening (invitation, screening test administration, diagnosis and treatment of screen positives) on individual basis, the **individual basis data collection**? The most organized form of such information system is a **screening registry** that collects data on each individual participating in screening.

If no, please go to Question 3.2 directly.

3.1.1 If yes, please indicate for which purpose the information system exists. You may enter multiple responses.

3.1.2 If "yes" for question 3.1, please indicate whether the information system is a unified one covering the screening programmes of the entire country (national) or covers only the sub-national programme (sub-national)? If there are separate information systems at national level and also at sub-national levels please select "both national and sub-national".

3.2 Is there a computerized or paper-based system that collects **aggregated data** only (grouped collection instead of individual data collection enabling an overall view of the programme)? The paper-based system works through maintaining registers of the screened individuals at different levels of facilities. If no, please go to Question 3.3 directly.

3.2.1 If yes, please indicate for which purpose the information system exists. You may enter multiple responses.

3.2.2 If "yes" for question 3.2, please indicate whether the information system is a unified one covering the screening programmes of the entire country (national) or covers only the sub-national programme (sub-national)? If there are separate information systems at national level and also at sub-national levels please select "both national and sub-national".

3.3 Is there a system collecting screening information outside the screening programme (e.g. **opportunistic screening** activities, etc.)? If the information can't be differentiated from opportunistic screening or from population-based screening, please select "cannot differentiate".

3.4 If **population-based cancer registries (PBCRs)** exist**,** are the screening **data linked with PBCR** via a matching criterion (e.g. national identity number or nominal data)?

3.5 If there is other information related to information system and data collection, please indicate here (e.g. quality control of data collection, the progress of the linkage between PBCR and screening registry, etc.).

4. Screening protocol

*In this section, please provide some information on **screening protocol** (including screening test, screening interval etc.).*

4.1 Please indicate if there is a screening protocol or not. If you have a documented screening protocol, please provide the link (if available) or email the electronic document to canscreen5@iarc.fr. If no screening protocol, please leave the section blank, go to Question 5.1 directly.

4.2 Please indicate the specific year when the current protocol was developed or last updated (indicate the most recent year). If no documented protocol, please indicate 9999. If unknown, please indicate 0000.

4.3 Please provide information on the screening protocol in the field of 4.3.1-4.3.4. Breast cancer screening may have different protocols using different primary screening tests (or their combinations) targeting different age groups. If there is a single protocol enter it in the field 4.3.1. If there are multiple protocols targeting the same or different age groups, please provide this information in fields 4.3.1-4.3.4 as appropriate. If there is no upper age limit, the upper age should be marked as 99. Please indicate the **screening interval** (in months) between routine rounds of screening as specified in the screening programme policy (12 = 1 year, 24 = 2 years, etc.) accordingly.

4.4 If mammography is used as a screening test, are the mammograms read by two radiologists independently, unaware of each other's findings?

4.5 If there is other information related to screening protocol uncovered by the section 4, please indicate here (e.g. a different screening protocol not based on age, but for selected population – hereditary cancer, familial history, high risk population etc.).

5. Invitations for screening and further assessment

In this section, you will provide information on screening invitation and further assessment.

5.1 To improve population awareness, are there any education initiatives conducted by Healthy Ministry/Health Authority, including **mass media campaign**, **small media campaign**, **group education**, **one-on-one education**?

If no, please go to Question 5.2 directly.

5.1.1 If yes, please indicate the specific education initiative(s). You may enter multiple responses.

5.2 For **individual invitation**, is there a system to invite (by letter, email, SMS, phone calls, home visits, or other methods) all the eligible individuals to screening? If no, please go to Question 5.3 directly.

5.2.1 If yes, please indicate how the eligible individuals are identified, from a population register, the electoral roll, the list of General Practitioner (GP) or Primary Health Center (PHC), a list of an insurance company or others. You may enter multiple responses.

5.2.2 If "yes" for question 5.2, please indicate how the eligible women are invited to screening. You may enter multiple responses.

5.3 Some programmes may invite only women not screened in the round to improve compliance or only a selected population (high-risk or vulnerable) rather than all eligible individuals. If the programme invites only the selected women, please provide the criteria for it.

5.4 Is there the **active contact of screen-positive cases** to ensure compliance with further assessment? If all screen positive women are actively contacted as a routine, please select "yes, systematically". If no such system exists or if women may be contacted occasionally, please select "no or sporadically".

5.5 Is there the **active contact of cancer cases** to ensure compliance with further management? If all such women are actively contacted as a routine, please select "yes, systematically". If no such system exists or if women may be contacted occasionally, please select "no or sporadically".

5.6 Does the programme also collect information on stage (clinical or pathological) of the cancers detected through the programme? If the programme collect information on stage for all women diagnosed with cancer within the

programme, please select “yes, systematically”. If no information on stage is collected (or just for part of those women), please select “no or sporadically”.

5.7 Does the programme also collect information on treatment (surgery, radiotherapy, chemotherapy, etc) of the cancers detected through the programme? If the programme collect information on treatment for all women diagnosed with cancer within the programme, please select “yes, systematically”. If no information on treatment is collected (or just for part of those women), please select “no or sporadically”.

5.8 Please indicate any other information related to invitation and further assessment (e.g. women were provided the written information on benefits and harms of screening at the time of invitation; invitation include a fixed appointment date; invitation system excludes cases already diagnosed with cancer; etc.).

6 Quality Assurance (QA) of screening activities

*In this section, you would provide information about **Quality Assurance** of screening activities.*

6.1 Is there a document (may be a standalone document or part of protocol or action plan for the programme) indicating the specific actions to be undertaken by the programme managers and the service providers to assure quality of the screening programme?

If yes, please provide the link (if available) or email the document to canscreen5@iarc.fr

6.2 Is there a person/team/institution responsible for quality assurance of the screening service delivery?

If no, please go to Question 6.3 directly.

6.2.1 If yes**,** please indicate the name of the specific team/institution responsible for the cancer screening activities. For individual, please provide his/her job position.

6.3 Do the mammography units participating in screening have a system of **accreditation**?

6.4 Please indicate if there is a system of accreditation for pathology services.

6.5 Is there a list of **performance indicators** (e.g. screening coverage, participation rate, further assessment rate, detection rate, positive predictive value, etc.) specified by the programme to assess the performance of screening activities and are these indicators used to systematically evaluate the performance?

If no, please go to Question 6.6 directly.

6.5.1 If yes, are the **reference standards** defined for some of the indicators? (e.g. examination coverage to be achieved).

6.6 Was the performance report of the screening programme published in last five years?

If yes, please provide the link (if available) or email document to canscreen5@iarc.fr

6.7 If there is other information related to quality assurance not covered by this section, please indicate here (e.g. the key performance indicators and their standards).

Appendix I **Definitions**

Sub-national

Sub-national level indicates any government entity below the national level, regardless of the political, financial and administrative design of the country (e.g. province, state, cantonal level, etc.).

Screening policy

A policy for a specific screening programme that specifies the government's commitment to provide screening services and defines the targeted age group and sex group, the geographical area, and other eligibility criteria; the screening test and interval; and requirements for payment or co-payment, if applicable. As a minimum, the screening protocol and repeat interval and determinants of eligibility for screening are stated.

Pilot programme

Pilot programme indicates a small scale implementation of screening programme to assess feasibility, impact on health services, barriers and facilitators of participation, etc. The Ministry of Health/Health Authority is committed to implement a screening programme and has a well-defined plan to scale up the programme based on the lessons learnt from the pilot. All the elements of screening programmes are fully functional at the time of implementing the pilot.

A pilot programme should be differentiated from a *demonstration project*. A demonstration project is implemented to test a hypothesis (e.g. mammography-based screening is feasible and cost-effective in a specific setting) and there is no commitment to scale up the screening services.

Screening programme

Defined as cancer screening performed in the framework of a publicly mandated programme. To be considered a 'programme' there has to be a commitment from the government to provide the screening services free of charges to the eligible population as defined by laws, statutes, regulations, or official notifications. In such cases, the eligible population, the screening test, and the screening interval, at a minimum should be defined and there should be some mechanism for monitoring and supervision.

Screening test, diagnosis, treatment free of charge

Public funding (with or without co-payment by insurance) to ensure no immediate payment by the individual for availing the screening, diagnosis, treatment services.

Further assessment

Additional diagnostic techniques (either immediately after screening or postponed in a referral setting) performed to confirm the nature of a perceived abnormality detected at the screening examination. Further assessment may take place on the same day as the screening examination or on recall. Examples: repeat smears, HPV testing, colposcopy, histology, ultrasonography, and colonoscopy.

Individual basis data collection

An information system that enables the follow-up of the care path and history of each individual enrolled in the programme (data from screening, diagnosis, and treatment).

Screening registry

The Cancer Screening Registry is any type of information system (computerized or paper-based) for the collection, storage, analysis and reporting of cancer screening programme data.

The registry supports the screening programmes by:

- Maintaining a database of screening records of individuals;
- Holding a single, consistent, national screening history for each participant;
- Inviting eligible persons to commence screening;
- Reminding participants when they are due and overdue for screening;
- Providing a 'safety net' for participants who are at risk and have not attended further testing, by prompting them (and the healthcare providers) to have follow-up tests.

Aggregated data
Grouped collected data that enable an overall view of the programme activity but do not include the individual details of the care path.

Opportunistic screening or non-population based screening
Screening can be population-based or non-population based, which is also known as opportunistic screening. Ideally screening should be provided through a population-based programme, in which there is a mechanism to identify each individual eligible to screening and invite them to undergo the tests. Screening outside a population-based screening programme, as a result of a recommendation made by a health-care provider during a routine medical consultation, or by self-referral of individuals is known as opportunistic screening. Such examinations can be performed according to the public screening policies, where they exist.

Population-based cancer registries (PBCRs)
A PBCR systematically collects information from multiple sources on all reportable neoplasms occurring in a geographically defined population. The purpose of a PBCR is to provide information on cancer burden and to assess possible causes of cancer in the community, as well as to carry out studies on prevention, early detection and screening, and cancer care. The registry provides a profile of the cancer burden in the population and how it changes over time, and therefore plays a unique role in the planning and evaluation of cancer control programmes.

Data linked with cancer registries
Data of individuals enrolled in the programme linked with the cancer registry data using the matching criteria (national identity number or nominal data).

Screening protocol
A screening protocol is a detailed documented plan on how to deliver the screening activities. As a minimum, the screening protocol should include clear information on the eligible individuals, target age, screening test, examination intervals, further assessment, referral system, and quality assurance. It should be integrated into the screening policy.

Screening interval
The interval between two screening episodes (round), within a screening programme or in an opportunistic setting.

Mass media campaign
Informational or motivational messages delivered to large audiences through broadcast and print media (television, radio, billboards, magazines, newspapers and internet).

Small media campaign
Informational or motivational messages delivered to individuals through brochures, leaflets, newsletters, letters, flip-charts, videos, social media, mobile phone, text message, short message service (SMS).

Group education
Informational or motivational messages delivered to an assembled group in lecture or interactive format by trained lay people or health professional.

One-on-one education
Informational or motivational messages delivered by one individual to another, either in person or by telephone. Maybe supported by small media or client reminders.

Individual invitation
An individual invitation (by letter, email, SMS, phone calls, home visits, or other methods) to the individuals in the eligible population to participate in the screening programme is sent by the coordination team, by primary health centres, or by general practitioners.

Active contact of screen-positive cases
Screen-positive individuals are actively contacted to ensure compliance with further assessment.

Active contact of cancer cases
Individuals with a diagnosis of precancer or cancer are actively contacted to ensure compliance with further management.

Quality assurance

Quality assurance encompasses activities intended to assure and improve quality at all levels of the screening process in order to maximize benefits and cost-effectiveness while minimizing harms. The concept includes the assessment or evaluation of quality, identification of problems or shortcomings in the delivery of care, the design of activities to overcome these deficiencies and follow-up monitoring to ensure effectiveness of corrective steps. Quality assurance of the screening process requires a robust system of programme management and coordination, assuring that all aspects of the service are performing adequately.

Accreditation

Accreditation is important for ensuring safety, quality and consistency of cancer screening activities. A series of initiatives are made to ensure cancer screening under a common set of standard, such as the peer review and evaluation of facility's staff qualifications, equipment performance, laboratory, pathology, endoscopy, radiology quality control and quality assurance programmes, image quality, dose and processor quality control.

Performance indicator

Performance indicators (PI) are measurable values that demonstrate how effectively a cancer screening programme is achieving its main objectives. The aim purpose of PI is to assess and monitor the quality and the possible impact of a cancer screening programme. These PI include screening coverage, participation rate, further assessment rate, detection rate, positive predictive value, etc.

Reference standards

The reference standards for indicators should be based on the achievable performances of well-established screening programmes (e.g. the acceptable level, the desirable level). Enlisting the minimum acceptable standards for the core indicators will greatly help the new programmes to organize their strategies and quality assurance plan. It is also essential to score the harms (and not achieved benefits), which are associated with poor performance.

General instructions

Thanks for your support and collaboration to CanScreen5 project. The present document will guide you to collect and submit quantitative data on breast cancer screening in the country/regions you are reporting for. The quantitative data mainly focuses on the target population, screening test outcomes, further assessment outcomes, treatment, etc. It will be convenient to collect data using this quantitative data collection form before submitting the same to the online platform of CanScreen5. **Terms in bold and underlined have a definition at the end of the corresponding page.** If you require assistance in filling any of the data forms, please contact us by email at canscreen5@iarc.fr

We would prefer to receive the programme annual screening data (inclusion of participants during a one year period for primary screening test, e.g. 01/01/2017 to 31/12/2017 with index year 2017 or 15/04/2018 to 14/04/2019 with index year 2018), which might be not the current or the last year, as it takes time to get further assessment information and to be completed and validated(meaning data checked for missing values, discrepancy, etc.). Otherwise, you can submit the data for the most recent round of screening.

Please fill in the general information as below:

1.	**General information**	
1.1	Country: _____	
1.2	Reporting for: *(1. national; 2. **sub-national**)*	[ ]
1.3	Name of the geographic area(s) if not reporting for entire country: _____	
1.4	If you are reporting not for entire country, are you reporting for a **pilot programme**, **demonstration project** or a research study? *(1. pilot programme; 2. demonstration project; 3. research study; 4. other_____)*	[ ]
1.5	Source: *(1. directly from programme (managed by Health Ministry/Health Authority); 2. official report (published by programme or Health Ministry/Health Authority); 3. peer-reviewed publication; 4. other reports (published by NGO/academic institutions); 5. other_____)* *(Please provide link (if available) or email the document to canscreen5@iarc.fr): _____*	[ ]
1.6	The period of reporting? (From mm/yyyy to mm/yyyy): [ ][ ]/[ ][ ][ ][ ] to [ ][ ]/[ ][ ][ ][ ]	
1.7	The **screening protocol** you are reporting for: *(If you want to submit data for programmes that use different screening protocols, please fill in different forms reporting for each protocol).* Primary screening tests: *(1. mammography (Mx) or digital breast tomosynthesis (DBT); 2. (Mx or DBT) + (clinical breast examination (CBE) or ultrasound (US)); 3. CBE + US; 4. US; 5. CBE)*	[ ]
1.8	Data by age group: *(1. 5 years age group; 2. 10 years age group; 3. no age stratification)*	[ ]

_____

Sub-national: Any government entity below the national level, regardless of the political, financial and administrative design of the country (e.g. province, state, cantonal level, etc.).

Pilot programme: A small scale implementation of screening programme to assess feasibility, impact on health services, barriers and facilitators of participation, etc. The Ministry of Health/Health Authority is committed to implement a screening programme and has a well-defined plan to scale up the programme based on the lessons learnt from the pilot. All the elements of screening programmes are fully functional at the time of implementing the pilot.

Demonstration project: The project is implemented to test a hypothesis (e.g. mammography-based screening is feasible and cost-effective in a specific setting) and there is no commitment to scale up the screening services.

Screening protocol: The protocol is a detailed documented plan on how to deliver the screening activities. As a minimum, the screening protocol should include clear information on the eligible individuals, target age, screening test, examination intervals, further assessment, referral system, and quality assurance. It should be integrated into the screening policy.

From here on, you will provide specific data about breast cancer screening and should fill out just one section of the table best representing the age-grouping data from the programme you are reporting. If the data is not stratified by age group, please fill out the last row only. CanScreen5 will prefer to get the data stratified by 5 yearly age groups. However, this is not mandatory. If you have no data for some specific age group, please leave it blank.

Are women personally invited? [ ]

1. yes (complete the column C, D); *2. no (keep the column C, D blank);*

Age group (years)	A	B	C	D	E
	Interval	Population	Invitation (if applicable)	Participation (if applicable)	Examination
	Screening interval (in months)	Nº of women in the target age	Nº of women invited during the reporting period	Nº of women screened among invited	Nº of women screened
Stratified by 5 yrs					
40-44					
45-49					
50-54					
55-59					
60-64					
65-69					
70-74					
75-79					
Other					
Stratified by 10 yrs					
40-49					
50-59					
60-69					
70-79					
Other					
No age stratification					
All in target age					

- **Column A: Screening interval (in months):** What's the screening interval as per the protocol?
- **Column B: Target population**: What's the total target population of the programme?
- **Column C: Invitation**: How many women were invited during the reporting period? Only the primary screening invitations were considered (**leave blank if there is no invitation**).
- **Column D: Participation**: How many women were screened of those invited during the reporting period? (**leave blank if there is no invitation**).
- **Column E: Examination**: How many women were screened during the reporting period, **irrespective of invitation**? Please note that the numbers in this column may be the same as the numbers in column D, if women were screened after invitation only.

Screening interval: The interval between two screening rounds, within a screening programme or in an opportunistic setting.

Target population: Total number of age-eligible individuals obtained from official statistics (irrespective of the screening interval) residing in the catchment area of a screening programme as defined by the screening policy).

Invitation: Invitation (by letter, email, SMS, phone calls, home visits, or other methods) to the individuals in the eligible population to participate in the screening programme is sent by the coordination team, by primary health centres, or by general practitioners.

For how many individuals can you provide test outcomes? [ ]

1. for all individuals screened during the index year (keep the column F blank);
2. for a subset of individuals screened (complete the column F);

Age group (years)	F	G	H	I
	Screening test outcomes			
	If a subset, Nº of women screened with test outcomes known	Nº of women with positive test outcomes	Nº of women with negative test outcomes	Nº of women with inconclusive test outcomes
Stratified by 5 yrs				
40-44				
45-49				
50-54				
55-59				
60-64				
65-69				
70-74				
75-79				
Other				
Stratified by 10 yrs				
40-49				
50-59				
60-69				
70-79				
Other				
No age stratification				
All in target age				

- **Column F: Number of women screened for whom the test outcomes are known:** Out of the women screened, for how many do you have test results available (including the inconclusive results)?
  The numbers in Column F may be: i) the same as the numbers in Column E, if this is the case, please leave it blank, ii) a subset of the numbers in Column E, for which the test results are available.
- **Columns G, H, I: Number of women with different test outcomes:** Out of those women screened and with results available, how many had:
  - A positive testing result? (BIRADS 3,4,5 for mammography and ultrasound)
  - A negative testing result? (BIRADS 1,2 for mammography and ultrasound)
  - A inconclusive/unsatisfactory testing result? (includes BIRADS 0)

For how many individuals with positive results can you provide further assessment performance? [ ]

1. for all individuals screened positive during the index year (keep the column J blank);
2. for a subset of individuals screened (complete the column J);
3. none (stop filling the form)

Age group (years)	J	K	L
	Further assessment		
	If a subset, Nº of women with positive test outcomes with further assessment outcomes	Nº of women with further assessment performed	Nº of women without further assessment performed
Stratified by 5 yrs			
40-44			
45-49			
50-54			
55-59			
60-64			
65-69			
70-74			
75-79			
Other			
Stratified by 10 yrs			
40-49			
50-59			
60-69			
70-79			
Other			
No age stratification			
All in target age			

- **Column J: Number of women with positive test outcomes for whom the <u>further assessment</u> outcomes are known**: Out of the women with a positive screening test as mentioned above, for how many do you have information of further assessment, including further assessment performed and not performed women? *The numbers in Column J may be: i) the same as the numbers in Column G, if this is the case, please leave it blank, ii) a subset of the numbers in Column G, for which the test results are available.*
- **Column K, L: Further assessment information:** Out of the screen positive women with information of further assessment available,
  - How many had a further assessment performed?
  - How many did not have any further assessment performed?

<u>Further assessment</u>: Additional diagnostic techniques (either immediately after screening or postponed in a referral setting) performed to confirm the nature of a perceived abnormality detected at the screening examination. Further assessment may take place on the same day as the screening examination or on recall. Examples: repeat smears, HPV testing, colposcopy, histology, ultrasonography, and colonoscopy.

For how many individuals can you provide histopathology outcomes? [ ]

1. for all women with further assessment performed with distinct CIS and Invasive cancer data (use column N and O);
2. for all women with further assessment performed with indistinct CIS and Invasive cancer data (use column O only);
3. for a subset of women with further assessment performed with distinct CIS and Invasive cancer data (use column M, N and O);
4. for a subset of women with further assessment performed with indistinct CIS and Invasive cancer data (use column M and O);
5. none (stop filling the form)

Age group (years)	M	N	O
	Outcomes of histopathology		
	If a subset, Nº of women with histopathology outcomes known	Nº of women with carcinoma in situ (CIS)	Nº of women with invasive breast cancer
Stratified by 5 yrs			
40-44			
45-49			
50-54			
55-59			
60-64			
65-69			
70-74			
75-79			
Other			
Stratified by 10 yrs			
40-49			
50-59			
60-69			
70-79			
Other			
No age stratification			
All in target age			

- **Column M: Number of women with known histopathology outcomes**: Out of the women with further assessment as mentioned above, for how many do you have information on histopathology?
  The numbers in Column M may be: i) the same as the numbers in Column K, if this is the case, please leave it blank, ii) a subset of the numbers in Column K, for which the test results are available.
- **Column N, O: Outcomes of histopathology information**: Out of those women further assessed and for whom you have **histopathology** results available, how many were
  - Detected to have CIS?
  - Detected to have invasive breast cancers?

For how many individuals can you provide stage outcomes? [ ]

1. for all individuals with CIS and/or invasive cancer (keep the column P blank);
2. for a subset of individuals with CIS and/or invasive cancer (complete the column P);
3. none (stop filling the form)

Age group (years)	P	Q	R	S	T	U	V
	Stage						
	If a subset, № of women with stage information known	Stage 0	Stage I	Stage II	Stage III	Stage IV	Stage not done
Stratified by 5 yrs							
40-44							
45-49							
50-54							
55-59							
60-64							
65-69							
70-74							
75-79							
Other							
Stratified by 10 yrs							
40-49							
50-59							
60-69							
70-79							
Other							
No age stratification							
All in target age							

- **Column P: Stage information**: Out of the women with CIS/invasive cancer, for how many do you have information on stage, which should be based on the TNM system?
- **Column Q-V: Different Stage**: Out of the women with stage information the distribution of stage was as follows:
  - Stage 0
  - Stage I
  - Stage II
  - Stage III
  - Stage IV
  - Stage not done

For how many individuals can you provide information on whether they have initiated cancer directed treatment or not? [ ]

1. for all individuals with CIS and/or invasive cancer (keep the column W blank);
2. for a subset of individuals with CIS and/or invasive cancer (complete the column W);
3. none (stop filling the form)

Age group (years)	W	X	Y
	Treatment		
	If a subset, Nº of women initiated treatment or not	Nº of women initiated treatment	Nº of women not initiated treatment
Stratified by 5 yrs			
40-44			
45-49			
50-54			
55-59			
60-64			
65-69			
70-74			
75-79			
Other			
Stratified by 10 yrs			
40-49			
50-59			
60-69			
70-79			
Other			
No age stratification			
All in target age			

- **Column W: Treatment information**: Out of the women with CIS/invasive cancer, for how many do you have information that the women initiated cancer directed treatment or not?
- **Column X, Y: Treatment status**: Out of those women with information on initiated cancer treatment or not, how many were
  - initiated treatment?
  - not initiated treatment?