swiss cancer screening

NATIONAL MONITORING OF ORGANISED MAMMOGRAPHY SCREENING PROGRAMMES IN SWITZERLAND; CONCEPT AND METHODOLOGY

Type	**Harmonisation / Harmonisierung**
Classification[1]	**Résultats**
Numéro	**P2/3**
Rédacteur	**Fanny Theytaz**
Validation	**Conférence des responsables des programmes**
Date d'entrée en vigueur	**27.05.2020**
Prochaine révision	**Selon besoin au plus tard le 27.5.2022**

Version 1.0 from 13.05.2020

[1] Selon le concept « Système Assurance Qualité » de SCS, il y a trois types de directives « **S**tructures » (S) ; « **P**rocessus » (P) et **R**ésultats « R ».

swiss cancer screening

Index

1. Introduction

Routine screening offers an examination to detect a specific disease at an early stage in a group of asymptomatic people. The main goal of organised mammography screening programmes is to decrease mortality from breast cancer. It is therefore imperative to ensure that those invited to take part in screening programmes are given the best quality service and adequate information about screening. Therefore, screening programmes must adhere to strict quality criteria and regular assessment to verify whether these quality criteria are achieved.

2. Background

2.1. Process and working group

This document is based on the breast monitoring concept 2013-2015. Contributing authors are:

- Bulliard Jean-Luc, Center for primary care and public health, (*unisanté)*, University of Lausanne*.*
- de Wolf Chris, Agence pour le développement et évaluation des politiques de santé, Genève (ADSAN Sarl).
- Fracheboud Jacques, Erasmus University Medical Center, Rotterdam.
- Herrmann Christian, Brustkrebs-Früherkennung des Kanton Sankt-Gallen.
- Mariéthoz Ewa, formerly Swiss Cancer Screening.
- Ocaña Manuela, Swiss Cancer Screening.
- Spitale Alessandra, Centro programma screening Ticino.
- Theytaz Fanny, Swiss Cancer Screening.
- Weiss Claudia, Swiss Cancer Screening.
- Zwahlen Marcel, Institute of Social and Preventive Medicine, University of Bern.

2.2. Breast screening cancer in Switzerland

2.2.1. Organized mammography screening in regional programmes

In Switzerland cantons are responsible to organize and carry out breast cancer screening. By 2010, the following cantons implemented organized programmes: Vaud, Valais, Genève, Fribourg and the region BEJUNE (French-speaking part of Bern canton, Jura and Neuchâtel). In 2010, two German-speaking programmes were implemented: St-Gallen and Thurgau, followed by Graubünden in 2011, the German-speaking part of Bern in 2013, Basel-Stadt in 2014 and finally Ticino in 2015. [1]

In Switzerland, organised mammography screening competes with opportunistic screening.

2.2.2. Regulatory framework

The quality standards are built on the legal bases in force and the regulations on the division of tasks between the Confederation and the cantons according to the Swiss Constitution. The cantons manage the provision of health care for their population (this includes prevention and screening). They bear political responsibility for the organisation of screening programmes and their financing. The Confederation regulates quality aspects and financial contributions through the compulsory health insurance scheme (OPAS) via the health insurance scheme OAMal RS 832.10[2]. At present, the OPAS covers the medical costs of mammography carried out in the

[1] Buillard J-L, Fracheboud J, Zwahlen M. Breast cancer screening programmes in Switzerland. Final report December 2018

event of a positive family history or as part of a screening programme (women aged 50 and over every two years).

Other legal regulations relevant for organised breast cancer screening are the Federal Data Protection Act (LPD), the Federal Radiological Protection Act (LRap) and the Federal Act on the Registration of Oncological Diseases (LEMO), which regulates the nation-wide registration of cancer introduced in 2020. The training of physicians involved in screening is subject to the Federal Law on Academic Medical Professions (LPMéd). In addition, cantonal programmes are governed by cantonal laws.

A broad group of experts under the leadership of the Swiss Cancer League drafted new quality assurance standards in 2014[3] (hereafter: CH Standards). These standards took into account the specific Swiss context and the 4th Edition of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis (hereafter, EU Standards). They are considered as “best practice” and are progressively implemented by all organized screening programmes in Switzerland.

3. Aim and process of monitoring

3.1 General objective

The general objective of Swiss national monitoring is to evaluate the effectiveness and quality of the breast cancer screening programmes in Switzerland at regular intervals. It is possible to initiate additional reports in case of unexpected results or major changes in screening policy.

The specific objectives of the national monitoring are:

- To inform about the development and the main outcomes of the programmes at national level;
- To provide transparent information about the implementation of European quality standards for screening mammography;
- To supply the interim measures that can be used for current and future assessments of organized breast cancer screening programmes;
- To allow inter-cantonal and international comparisons.

This allows to assess at a given time in a uniform way the performance of programmes. With predefined outcomes and identical quality indicators, harmonization of quality assurance as well as a uniform monitoring/evaluation can be reached.

3.2 Actors and responsibilities

Swiss Cancer Screening (SCS): initiates the monitoring, mandates experts and provided an IT and workflow management tool used by all programmes for harmonized data collection.

Data provider: software provider CDI is responsible for data extraction after the programmes have given their consent.

Evaluator: Jean-Luc Buillard has been mandated to carry out the monitoring. He receives the extracted aggregated data for analysis.

Reporting experts: Jean-Luc Buillard, Jacques Fracheboud and Marcel Zwahlen interpret the data and provide the scientific report.

[3] Normes de qualité pour le dépistage organisé du cancer du sein en Suisse, Ligue Suisse contre le cancer, 2014

3.3 Timeline

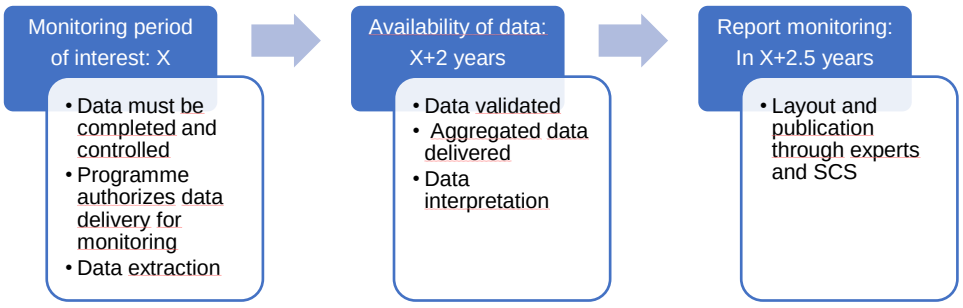

Figure 1: Timeline for monitoring process

4. Methodology

4.1 Target population

All women residing in the programme canton(s) are eligible from the age of 50 to 69/74* (determining factor: year of birth). With a screening interval of two years, half of the target group is invited every year. An invitation for mammography screening is sent to women from the age of 50. With the personal invitation to a screening every 24 months, the invited women receive a balanced and scientifically sound information leaflet about the screening procedure and its benefits and risks.

4.2 Examination

Invited women are free to choose one of the accredited radiological centres from a list attached to the invitation letter. The screening examination, which consists of a two-view mammography, is conducted in either a hospital or in a private or public radiology centre which are accredited for mammography screening. The reading and interpretation of the mammography is performed by two independent radiologists. If a first and a second reader disagree in the interpretation, a third radiologist is consulted as an arbitrator or the case is discussed in a consensus conference. In case of women with dense breasts and negative screen, an additional echography is systematically recommended.

4.3 Data governance

4.3.1 Database structure and data security

In 2015, a common and single IT-solution, MC-SIS (Multi cancer screening information system) was implemented in all existing cantonal screening programmes[4] and previously collected data were migrated into it[5]. The primary data related to the invitation, exclusion criteria (non-eligibility), 1st/2nd readings of the screening mammograms, diagnostic process in screen-positive women are directly collected within MC-SIS. The secondary data are obtained from the population registry and cancer registry according to cantonal procedures. The data

* until 69 years old: St-Gallen, Graubünden, Ticino
until 74 years old: Basel-Stadt, German-speaking part of Bern, Fribourg, Genève, BEJUNE, Thurgau, Valais, Vaud

[4] SCS Security concept. Available on request for SCS members.
[5] Some inconsistencies between the previous data base (MF-SIS) still exists, mainly related to the nomenclature.

gathered by each programme are hold in separate databases. The database security measures are described in the Security concept MC-SIS.

4.3.2 Harmonization process

In order to avoid cantonal specificities in the data acquisition that could impair the data quality, SCS implemented some simple measures. Information sessions and exchange meetings between MC-SIS users (health professionals and programme administrators) are organised regularly to develop a common understanding of data quality.

4.3.3 Data extraction and validation

The monitoring period of interest is defined as year X, consisting of one or more calendar years and "X" standing for the most recent calendar year of this period. At the end of January of year X+2, the data managers have validated the data for the monitoring period up to and including year X and verified their accuracy. Authorization for data transfer and processing with respect to the relevant time period for each programme is transmitted to SCS.

Data will be extracted by CDI in February of the year X+2. Only anonymized and aggregated data will be available for SCS.

5. Variables and indicators

Each programme monitors its performance at the cantonal/regional level. Relevant indicators are reported in the national monitoring. Indicators used in this report are based on EU standards[6] covering all steps of the screening process[7]. At regular interval, SCS publishes on 17 indicators and compares the results with predefined CH/EU Standards. The way each indicator is constructed is indicated in a specific meta-sheet (see annex I, Variables and Indicators).

- *Participation* indicators or *programme/ process* indicator: assess the acceptance and adherence of women to the screening programme.

- *Performance* indicators or *quality* indicators: reflect provision and quality of activities constituting screening process without contributing directly to reduction in mortality. It is important to record data elements as well as produce and monitor indicators regularly. This is the basis of quality assurance activities within and across specialities.

- *Prognostic* indicators or *early impact* indicators: indicative of whether breast cancer screening might achieve the objective of reducing breast cancer mortality in the long-term.

[6] European guidelines for quality assurance in breast cancer screening and diagnosis, 4th edition, 2006
[7] Quality Assurance Scheme Development Group. European Quality Assurance scheme for Breast Cancer Services. http://ecibc.jrc.ec.europa.eu/documents/20181/45343/European+QA+scheme+scope.pdf/9c1362f1-160e-4869-8356-42525521e700

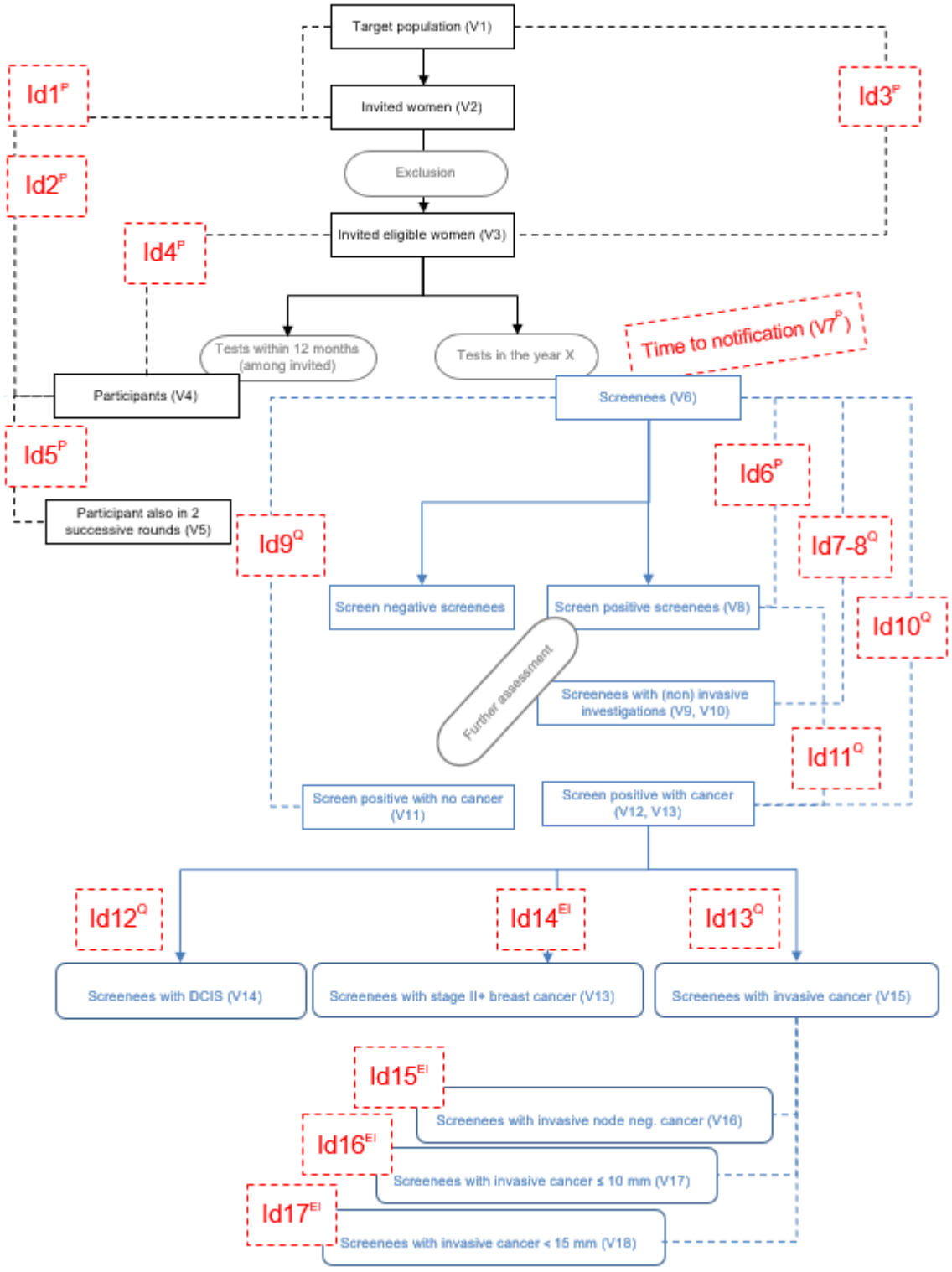

Figure 2: Summary of Swiss breast cancer national monitoring

P: Process indicators; Q: Quality indicators; EI: early Impact indicators

In Switzerland, there is no consensus on eligibility criteria for invitation to screening. The majority of the working group has proposed to compute the *participation rate* or *coverage by invitation rate* not adjusted by ineligibility. The minority of the working group has suggested to adjust the denominator by eligibility in order to get a more precise participation or coverage by invitation rate. The monitoring report 2013-2015 used both indicators and concluded that the

number of ineligible women was negligible (<0.5%[8]). Therefore, forthcoming reports will present the *participation rate* and *coverage by invitation rate* not adjusted by eligibility. In this document the definitions of both indicators, adjusted or not by eligibility, are provided.

6. Update of this document

Due to new developments, such as changes in screening policy, updates of guidelines (EU Standards, AJCC, etc) or regulations, it might be necessary to add new indicators and or modify indicator definitions. Therefore, this document will be reviewed every 2 years by SCS in collaboration with programmes and experts, taking into account all relevant new aspects regarding the monitoring.

6.1 Proposed process

- To start with a consultancy round by e-mail: what must be updated (history), are there new relevant regulations, documents or references? Additional indicators needed? Indicator definitions to be modified? Modifying monitoring process?
- Draft review document
- Meeting to finalize document
- Reviewed document to be accepted: by experts, SCS and working group
- Reviewed document is distributed to all programme leaders for final approval.

7. Further steps

Unlike the cantonal reporting and/or the long-term evaluation, the national monitoring provides a rough picture of the organized breast-cancer screening programmes outcomes. In order to fulfill its aims, summarized in Section 3, the national monitoring should be produced frequently and timely enough to allow an adequate analysis of the results and the implementation of the mitigation and/or corrective measures.

The national monitoring is currently based on 17 indicators and concerns at least 12 independent programmes. All data processing concerning the monitoring should be automatized through queries and data reporting tools in order to minimize the work load of all people involved in the monitoring process.

8. Acknowledgements

SCS is indebted to the authors Jean-Luc Buillard, Jacques Fracheboud, Fanny Theytaz and Marcel Zwahlen for drafting and revising this document. SCS also thank the members of the quality group Chris de Wolf, Christian Herrmann, Ewa Mariéthoz, Manuela Ocaña, Alessandra Spitale and Claudia Weiss for their outstanding support. Valuable comments were received from Béatrice Arzel.

9. References

Bulliard J-L, De Landtsheer JP, Levi F. Results from the Swiss mammography screening pilot programme. *Eur J Cancer* 2003; 39(12), 1761–9.

[8] Bulliard J-L, Fracheboud J, Zwahlen M. Breast cancer screening programmes in Switzerland. Final report December 2018

Bulliard J-L, Ducros C, Jemelin C, Arzel B, Fioretta G, Levi F. Effectiveness of organized versus opportunistic mammography screening. *Ann Oncol* 2009; 20, 1199-202.

Bulliard J-L, Ducros C, Dayer E, Arzel B, Levi F. Variation in performance in low-volume mammography screening programmes: experience from Switzerland. *Cancer Epidemiol*; 2011; 35, 293-7.

Bulliard JL, Zwahlen M, Fracheboud J. Dépistage par mammography en Suisse, Année 2010. Mammographie screening Schweiz, 2010. Bern: Swiss Cancer Screening, Juillet 2013.

Bulliard JL, Zwahlen M, Fracheboud J. Dépistage par mammography en Suisse, Année 2011. Mammographie screening Schweiz, 2011. Bern: Swiss Cancer Screening, Septembre 2014.

Bulliard JL, Zwahlen M, Fracheboud J. Dépistage par mammography en Suisse, Année 2012. Mammographie
screening Schweiz, 2012. Bern: Swiss Cancer Screening, Février 2016.

Bulliard J.L. 2015. Rapport du monitoring 2012 des programmes suisses de dépistage du cancer du sein – un bref bilan. Institut universitaire de médecine sociale et preventive, Lausanne.

Bulliard J.L, Fracheboud J, Zwahlen M. 2018. Breast cancer screening programmes in Switzerland, 2010-2015. Available at info@swisscancerscreening.ch.

Dialogue Politique nationale suisse de la santé. Stratégie nationale contre le cancer 2014–2017.

European Guidelines for quality assurance in breast cancer screening and diagnosis (Perry et al., 2006, fourth edition).

Fracheboud J. Monitoring and evaluation of organised mammography screening in Switzerland. Final proposal. October 2010, Rotterdam.

IARC Handbook of Cancer Prevention Volume 15. Breast Cancer Screening. 2016.

Giordano L, Giorgi D, Frigerio A, Bravetti P, Paci E, Petrella P, Ponti A, Sassoli P. Programme indicators and standards for the evaluation of breast cancer screening programmes. *Epidemiologia & Prevenzione* 2006, 30(2) Supplemento 1.
http://www.epidemiologiaeprevenzione.it/materiali/ARCHIVIO_PDF/Suppl/2006/EP_V30I2S1.pdf

Herrmann C, Vounatsou P, Thürlimann B, et al. Impact of mammography screening programmes on breast cancer mortality in Switzerland, a country with different regional screening policies. BMJ Open2018;8:e017806. doi:10.1136/bmjopen-2017-017806.

Kemp Jacobsen K, von Euler Chelpin M,Vejborg I, Lynge E. Impact of invitation schemes on breast cancer screening coverage: A cohort study from Copenhagen, Denmark. *J Med Screen* 2017, 24(1) 20–26.

Krebsliga Schweiz. Qualitätsstandards für die organisierte Brustkrebs-Früherkennung in der Schweiz. Bern: Krebsliga Schweiz, 2014 (Hereinafter CH Standards).

Quality Assurance Scheme Development Group. European Quality Assurance scheme for Breast Cancer Services.http://ecibc.jrc.ec.europa.eu/documents/20181/45343/European+QA+scheme+scope.pdf/9c1362f1-160e-4869-8356-42525521e700.

Peisl S, Zimmermann S, Camey B, Betticher D and Bouchardy C. 2018. Comparison between opportunistic and organised breast cancer mammography screening in the Swiss canton of Fribourg. BMC Cancer (2019) 19:469 https://doi.org/10.1186/s12885-019-5706.

Siljander I, Heinävaara S, Sarkeala T, Pankakoski M, Anttila A. 2016. Definition of indicators. Finnish Cancer Registry, Helsinki. 5.7.2016. http://eu-topia.org/download/d2-2-definition-of indicators/?wpdmdl=356&ind=e0y6WO1u-ootAJM-N9gx0Sr1ZUHCbmFdKKVFGC6kExIut03V92unQSLzw2UnwIL7fnGexZO4L3qkGfQtnbWLug

swiss cancer screening

Annex I: Variables and indicators

Women in the 70-74 age group will be analysed separately, in an analogous manner to the 50-69 age group.

i. Meta-sheets of selected variables

V1	**Target population**
Group	n/a
Type (N°)	Variable (V1)
Definition	Number of women being minimally 50 and maximally 69 years old at invitation in year X, resident in the area covered by a programme.
Source of data	Federal Office of Statistics (https://www.bfs.admin.ch/bfs/fr/home/statistiques/population/effectif-evolution.assetdetail.5887433.html).
Part of indicator(s)	Denominator: Coverage by invitation (Id1). Denominator: Coverage by invitation adjusted by eligibility (Id3).
Subdivisions	
Revision history	Introduction: 6.03.2017.
Remarks	At the end of year X, not-adjusted for eligibility (such as deceased, moved off, cancer, etc) or refusal to participate.
V2	**Invited women**
Group	Invitation group
Type (N°)	Variable (V2)
Definition	Number of women invited in the year X.
Source of data	Invited women: Table EVAL_CHEMIN ETCODE (=”INVITATION” or “REMAINDER”) and DTREAL (date of invitation) Self-invited women: Table EVAL_CHEMIN ETCODE for INVITATION and REMAINDER are null (no invitation or remainder sent) Table EVAL_VAGUE DATE_EXAM not null (date of screening exam)
Part of indicator(s)	Numerator: Coverage by invitation (Id1). Denominator: Participation within 12 months (Id2).
Subdivisions	Number of initially invited women (V2a), Number of subsequently invited women (V2b), Number of self-invited women (V2c).
Revision history	Introduction: 6.03.2017.
Remarks	- Event REMAINDER used only for women with no event “INVITATION”

	- Including self-invitation for screening. - Not including reminder letters in year X. - Women refusing definitely to participate are not anymore invited and do not appear in V2 in the next round.
V3	**Invited eligible women**
Group	Invitation group
Type (N°)	Variable (V3)
Definition	Number of invited women being minimally 50 years old and maximally 69 years old in year X, resident in the area covered by a programme, adjusted by eligibility by December 31st. Criteria of eligibility - are alive, - domiciled in the programme area, - having a valid address, - not having had performed a mammography within last 12 months (software built-in exclusion criterion),
Source of data	Table EVAL_PARTICIPANT DT_NAISS (year of birth in the target age range) Table EVAL_ADRESSE PROGRAMME and CNUM (municipality of residence within the territory of the programme) Table EVAL_CHEMIN ETCODE (=”DECES” or "ADRESSE_INVALIDE" or "SORTIE_CANTON") and DTREAL (death or a current unknown residence prior to an INVITATION) ETCODE (=”EXCLUSION”) Table EVAL_VAGUE CLINICAL_ANOMALY_TYPE (=562 or 569) BREAST_TYPE (=1145)
Part of indicator(s)	Numerator: Coverage by invitation adjusted by eligibility (Id3). Denominator: Participation within 12 months adjusted by eligibility (Id4).
Subdivisions	Number of initially invited, eligible women (V3a), Number of subsequently invited, eligible women (V3b).
Revision history	Introduction: 13.11.2017.
Remarks	- *Ex-post* adjustment for eligibility may have an impact on the accuracy of the monitoring - Women refusing to participate are not anymore invited and do not appear in V2 in the next round.
V4	**Participants within 12 months**
Group	Invitation group
Type (N°)	Variable (V4)
Definition	Number of women having a screening mammography in the year X, within 12 months after invitation.
Source of data	Table EVAL_CHEMIN ETCODE (=”INVITATION” or “REMAINDER”) and DTREAL (date of invitation) Table EVAL_VAGUE DATE_EXAM (date of screening exam)

Part of indicator(s)	Numerator: Participation rate within 12 months (Id2). Numerator: Participation rate within 12 months adjusted by eligibility (Id4).
Subdivisions	Number of initial participants (V4a), Number of subsequent participants (V4b), Number of self-invited participants, for newly established programmes (V4c).
Revision history	Introduction: 6.03.2017.
Remarks	- REMAINDER used only for women with no date of INVITATION - This variable is used to calculate the participation rate (adjusted or not by eligibility) within 12 months. - This variable is not used to calculate other quality and prognostic indicators.
V5	**Number of participants in 2 successive rounds**
Group	Invitation group
Type (N°)	Variable (V5)
Definition	Number of participants invited in the year X having participated in 2 successive rounds.
Source of data	Table EVAL_CHEMIN NVAGUE (recalculated screening round) Table EVAL_VAGUE DATE_EXAM (date of screening exam)
Part of indicator(s)	Denominator: Re-attendance rate (ID5).
Subdivisions	
Revision history	Introduction: 6.03.2017.
V6	**Screenees**
Group	Screenee group
Variable and ID	Variable (V6)
Definition	Number of women having had a mammography in the year X.
Source of data	Table EVAL_VAGUE DATE_EXAM (date of screening exam)
Part of indicator(s)	Denominator: Breast cancer detection rate (Id6). Denominator: Non-invasive diagnostic investigation rate (Id7). Denominator: Invasive diagnostic investigation rate (Id8). Denominator: False-positive rate (Id9). Denominator: Recall rate (Id10).
Subdivisions	Number of initial screenees (V6a), Number of subsequent screenees (V6b).
Revision history	Introduction: 6.03.2017.
Remarks	Not related to the date of invitation.
V7	**Time from mammography to notification[9] of results**

[9] The date of notification is the date on which the letter is printed out by MC-SIS and ready for sending.

Group	Screenee group
Type (N°)	Variable (V7)
Definition	Number of working days between the mammography and the sending of the screening examination result (screen-positive or screen-negative) in screenees of year X.
Source of data	Table EVAL_CHEMIN ETCODE (=”INVITATION” or “REMAINDER”) and DTREAL (date of invitation) Table EVAL_VAGUE DATE_EXAM (date of screening exam)
Part of indicator(s)	
Subdivisions	
Revision history	Introduction: 6.03.2017.
Remarks/Rationale	- V7 is used as a process indicator. According to the article 9 of the ordinance[10], in order to prevent anxiety, women should receive the results within 8 working days from the date of the mammography.
V8	**Screen-positive screenees**
Group	Screenee group
Variable and ID	Variable (V8)
Definition	Number of screenees with a mammographic lesion who are recalled for further diagnostic assessment in order to clarify the nature of the lesion (malignant vs benign).
Source of data	Table EVAL_VAGUE DATE_EXAM (date of screening exam) Table EVAL_VAGUE CONCL (positive reading conclusion)
Part of indicator(s)	Nominator: Recall rate (Id10). Denominator: Positive predictive value (Id11).
Subdivisions	Number of initial screen-positive screenees (V8a), Number of subsequent screen-positive screenees (V8b).
Revision history	Introduction: 6.03.2017.
Remarks	
V9	**Screenees with non-invasive diagnostic investigations**
Group	Screenee group
Type (N°)	Variable (V9)
Definition	Number of screen-positive screenees being exposed to non-invasive diagnostic investigations (including MRI).
Source of data	MC-SIS.
Part of indicator(s)	Numerator: Non-invasive investigation rate (Id7).

[10] RS 832.102.4

Subdivisions	Number of initial screen-positive screenees with non-invasive diagnostic investigations (V9a), Number of subsequent screen-positive screenees with non-invasive diagnostic investigations (V9b).
Revision history	Introduction: 6.03.2017.
Remarks	Invasive diagnostic investigations are: Fine needle aspiration, core biopsy, open biopsy (exhaustive list). Any other procedure is considered as non-invasive.
V10	**Screenees with invasive diagnostic investigations**
Group	Screenee group
Type (N°)	Variable (V10)
Definition	Number of screen-positive screenees being exposed to invasive diagnostic investigations (see below).
Source of data	Table EVAL_VAGUE CONCL (positive reading conclusion) Table QMED_INVEST CDINVEST, CDRESULT and NOREGR (type of diagnostic investigation for any suspicious lesion and its result)
Part of indicator(s)	Numerator: Invasive investigation rate (Id8).
Subdivisions	Number of initial screen-positive screenees with invasive diagnostic investigations (V10a), Number of subsequent screen-positive screenees with invasive diagnostic investigations (V10b).
Revision history	Introduction: 6.03.2017.
Remarks	Invasive diagnostic investigations include (exhaustive list): - Fine needle aspiration - Core biopsy - Open biopsy
V11	**Screen positive screenees with no cancer detected by further diagnostic assessment**
Group	Screenee group
Type (N°)	Variable (V11)
Definition	Number of screen-positive screenees (recalled) in whom no breast cancer was detected by further diagnostic assessment.
Source of data	Table EVAL_VAGUE CONCL (positive reading conclusion) Table QMED_DIAG_LES CANCER (=1642 or 1644)
Part of indicator(s)	Numerator: False-positive rate (Id9).
Subdivisions	Number of false positives in initial screen-positive screenees (V11a), Number of false positives in subsequent screen-positive screenees (V11b).
Revision history	Introduction: 6.03.2017.

V12	Screenees with breast cancer[11]
Group	Screenee group
Type (N°)	Variable (V12)
Definition	Number of screen-positive screenees in whom breast cancer (DCIS or invasive) was diagnosed during diagnostic assessment.
Source of data	Table EVAL_VAGUE CONCL (positive reading conclusion) Table QMED_DIAG_LES CANCER (=1641)
Part of indicator(s)	Numerator: Breast cancer detection rate (Id6). Numerator: Positive predictive value (Id11). Denominator: Proportion of DCIS (Id12). Denominator: Proportion of invasive breast cancer (Id13). Denominator: Proportion of TNM-Stage II+ breast cancer (Id14).
Subdivisions	Number of initial screen-positive screenees with confirmed breast cancer (V12a), Number of subsequent screen-positive screenees with confirmed breast cancer (V12b).
Revision history	Introduction: 6.03.2017.
Remarks	Preferably breast cancer of confirmed histology[12]. Lobular carcinoma in situ is not considered a breast cancer but a lesion at risk (i.e. false-positive screening result).
V13	**Screenees with TNM-Stage II+ breast cancer**
Group	Screenee group
Type (N°)	Variable (V13)
Definition	Number of screen-positive screenees with confirmed breast cancer of TNM-stage greater or equal to II.
Source of data	Table QMED_DIAG_LES CANCER (=1641), GANGP and STADET
Part of indicator(s)	Numerator: Proportion of TNM-stage II+ cancer (Id14).
Subdivisions	Number of initial screen-positive screenees with confirmed breast cancer of TNM-stage greater or equal to II (V13a), Number of subsequent screen-positive screenees with confirmed breast cancer of TNM-stage greater or equal to II (V13b).
Revision history	Introduction: 6.03.2017.
Remarks	- TNM-Stage II+ cancers are often defined as advanced cancer (opposite to TNM-Stages I and 0 (in situ) which are early-stage cancers). - T1 cases with nodal micrometastases only (pT1 pN1mi) should not be included according to TNM AJCC, 8th Edition.
V14	**Screenees with DCIS**
Group	Screenee group

[11] All variables below are defined according to AJCC Cancer Staging Manual, 8th Edition.
[12] Histological confirmation is highly recommended to define a cancer diagnosis.

Type (N°)	Variable (V14)
Definition	Number of screen-positive screenees with confirmed[27] DCIS.
Source of data	Table QMED_DIAG_LES CANCER (=1641) and CDDIAG (all xxxx.2 codes except 8520.2)
Part of indicator(s)	Numerator: Proportion of DCIS (Id12).
Subdivisions	Number initial screen-positive screenees with confirmed DCIS (V14a), Number subsequent screen-positive screenees with confirmed DCIS (V14b).
Revision history	Introduction: 6.03.2017.
V15	**Screenees with invasive breast cancer**
Group	Screenee group
Type (N°)	Variable (V15)
Definition	Number of screen-positive screenees with confirmed screen-detected invasive breast cancer.
Source of data	Table QMED_DIAG_LES CANCER (=1641) and CDDIAG (any xxxx.3 code)
Part of indicator(s)	Numerator: Proportion of invasive breast cancer rate (Id13). Denominator: Proportion of node-negative cancer (Id15). Denominator: Proportion of invasive cancer ≤10 mm in size (Id16). Denominator: Proportion of invasive cancer <15 mm in size (Id17).
Subdivisions	Number of initial screen-positive screenees with confirmed screen-detected invasive breast cancer (V15a), Number of subsequent screen-positive screenees with confirmed screen-detected invasive breast cancer (V15b).
Revision history	Introduction: 6.03.2017
V16	**Screenees with node-negative invasive breast cancer**
Group	Screenee group
Type (N°)	Variable (V16)
Definition	Number of screen-positive screenees with confirmed[27] screen-detected invasive breast cancer without metastatic involvement of lymph nodes.
Source of data	Table QMED_DIAG_LES CANCER (=1641), CDDIAG (any xxxx.3 code) and GANGP
Part of indicator(s)	Numerator: Proportion of node-negative invasive breast cancer (Id15).
Subdivisions	Number of initial screen-positive screenees with confirmed screen-detected invasive breast cancer without metastatic involvement of lymph nodes (V16a), Number of subsequent screen-positive screenees with confirmed screen-detected invasive breast cancer without metastatic involvement of lymph nodes (V16b).
Revision history	Introduction: 6.03.2017.

Remarks	Invasive breast cancer with negative sentinel lymph-node should-be classified as “node-negative”.
V17	**Screenees with invasive breast cancer smaller or equal to 10 mm**
Group	Screenee group
Type (N°)	Variable (V17)
Definition	Number of screen-positive screenees with confirmed screen-detected invasive breast cancer smaller or equal to 10 mm in size.
Source of data	Table QMED_DIAG_LES CANCER (=1641), CDDIAG (any xxxx.3 code) and TAILLE
Part of indicator(s)	Numerator: Proportion of invasive breast cancer ≤10 mm (Id16).
Subdivisions	Number of initial screen-positive screenees with confirmed screen-detected invasive breast cancer ≤10 mm in size. (V17a), Number of subsequent screen-positive screenees with confirmed screen-detected invasive breast cancer ≤10 mm in size (V17b).
Revision history	Introduction: 6.03.2017.
Remarks	The pathological classification of cancer smaller or equal to 10 mm is defined according to the AJCC Cancer Staging Manual, 8th Edition.
V18	**Screenees with invasive breast cancer smaller than 15 mm**
Group	Screenee group
Type (N°)	Variable (V18)
Definition	Number of screen-positive screenees with confirmed screen-detected invasive breast cancer smaller than 15 mm in size.
Source of data	Table QMED_DIAG_LES CANCER (=1641), CDDIAG (any xxxx.3 code) and TAILLE
Part of indicator(s)	Numerator: Proportion of invasive breast cancer <15 mm (Id17).
Revision history	Introduction: 6.03.2017.
Remarks	The pathological classification of cancer smaller to 15 mm is defined according to the AJCC Cancer Staging Manual, 8th Edition.

ii. Meta-sheets for selected indicators

Id1	**Coverage by invitation (%)**	
Type (N°)	Indicator (Id1)	**KPI[13]: -**
Definition	The number of women invited by the programme as a proportion (%) of the target population.	
Rationale[14]	Id1 is a process indicator which informs on the accessibility to the programme.	
Calculation	Numerator: Invited women x 100	
	Denominator: Target population x 0,5	
Formula	$=\frac{v2}{0{,}5v1}$x100	
Target		
Subdivisions		
Revision history	Introduction: 6.03.2017.	
Remarks	- This indicator depends on numerous factors, such as programme-specific criteria for eligibility, invitation procedure, drop outs and technical aspects of the invitation scheme. - The target population is invited every 2 years (In Year X: 50% of the target population at the beginning of year X is invited). - More relevant for starting programmes.	
Id2	**12-month Participation rate (%)**	
Type (N°)	Indicator (Id2)	**KPI: 5**
Definition	The number of women who attend mammography screening in year X, as a proportion (%) of all women invited within the 12 preceding months.	
Rationale	Id2 is a process indicator. A high participation rate is necessary to reduce the breast cancer mortality at population level.	
Calculation	Numerator: Participants x 100	
	Denominator: Invited women	
Formula	$=\frac{v4}{v2}$x100	
Target	Initial and Subsequent screening (CH/EU Standards). Acceptable level: > 70%; Desirable level: > 75%.	
Subdivisions	Initial invitation Participation rate (Id2a), Subsequent invitation Participation rate (Id2b), Participation rate in self-invited women-(Id2c).	
Revision history	Introduction: 6.03.2017.	
Remarks	- “Opportunistic screening” among targeted women is not taken into account. - Contrary to Id4, Id2 takes into account all invited women.	

[13] The KPI numbers refer to the numbers presented in Summary table of Key Performance Indicators (p 11-14) of the EU Standards.
[14] Rationale= only for Indicators.

	- This indicator goes beyond EU Standards.	
Id3	**Coverage by invitation adjusted by eligibility (%)**	
Type (N°)	Indicator (Id3)	**KPI: -**
Definition	The number of invited, eligible women as a proportion (%) of the target population in year X.	
Rationale	Id3 is a process indicator which informs on the accessibility to the programme.	
Calculation	Numerator: Invited eligible women x 100	
	Denominator: Eligible women x 0,5	
Formula	$=\frac{v3}{v1x0,5}x100$	
Target Subdivisions Revision history	None Introduction: 13.11.2017	
Remarks	- The eligibility is assessed December 31st of year X. - This indicator takes into account the programme-specific criteria for eligibility.	
Id4	**12-month Participation rate adjusted by eligibility (%)**	
Type (N°)	Indicator (Id4)	**KPI: 5**
Definition	The number of eligible women who attend mammography screening in year X being invited within 12 months as a proportion (%) of all invited, eligible women in year X.	
Rationale	Id4 is a process indicator as a high participation rate contributes in reducing breast cancer mortality.	
Calculation	Numerator: Participants x 100	
	Denominator: Invited eligible woman	
Formula	$=\frac{v4}{v3}x100$	
Target	Initial and Subsequent screening (CH/EU Standards). Acceptable level: > 70%; Desirable level: > 75%.	
Subdivisions	Initial invitation Participation rate adjusted by eligibility (Id4a), Subsequent invitation Participation rate adjusted by eligibility (Id4b), Participation rate in self-invited women-(Id4c).	
Revision history	Introduction: 13.11.2107.	
Remarks	- “Opportunistic screening” among targeted women is not taken into account. - This indicator depends on programme-specific criteria for eligibility.	
Id5	**Re-attendance (%)**	
Type (N°)	Indicator (Id5)	**KPI: -**

Definition	The number of participants screened in 2 successive rounds (i.e. in the round X and the previous one) within 3 years, as the proportion (%) of participants of the previous round which have been re-invited in the current round (in year X).	
Rationale	Id5 is a process indicator of the screening programme as it provides feedbacks about how the participants have experienced the screening examination in the previous round. In fact, only regular participation can lead to an impact of mortality.	
Calculation	Numerator: Participants in both the previous and current rounds within 3 years x 100	
	Denominator: Participants of the previous round re-invited in the current round	
Formula	$=\frac{v5}{v4}x100$	
Target	None.	
Subdivisions		
Revision history	Introduction: 6.03.2017.	
Remarks	Id5 is also called “reattendance rate”.	
Id6	**Recall rate**	
Type (N°)	Indicator (Id6)	**KPI: 12**
Definition	Number of screen-positive (recalled) screenees for further assessment as a rate of all screenees in year X (per 1’000).	
Rationale	Id10 is an important quality indicator of the mammography image and interpretation. A high recall rate increases the number of diagnostic investigations and the number of examinations with a false-positive result.	
Calculation	Numerator: Screen-positive screenees x 1’000	
	Denominator: Screenees	
Formula	$=\frac{v8}{v6}x1’000$	
Target	Initial screening (CH/EU Standards): Acceptable level: <7%; Desirable level: <5% Subsequent screening (CH/EU Standards): Acceptable level: <5%; Desirable level: 3%	
Subdivisions	Recall rate in initial screening (Id10a), Recall rate in subsequent screening (Id 10b).	
Revision history	Introduction: 6.03.2017.	
Remarks	At subsequent screening rounds, the availability of previous screening images for comparison allows a better interpretation of the mammograms. Recall rates at subsequent screening rounds will therefore be consistently lower.	
Id7	**Non-invasive diagnostic investigation rate**	
Type (N°)	Indicator (Id7)	**KPI: -**

Definition	Number of screen-positive (recalled) screenees undergoing a non-invasive assessment as a rate of all screenees in year X (per 1'000).	
Rationale	Id 7 is a quality indicator that gives information on the risk to have a non-invasive assessment when participating in screening. Women with a retrospectively false-positive screening result should preferably undergo only non-invasive procedures.	
Calculation	Numerator: Screenees with non-invasive diagnostic investigations x 1'000 Denominator: Screenees	
Formula	$=\frac{v9}{v6}$x1'000	
Target		
Subdivisions	Non-invasive diagnostic investigation rate in initial screening (Id7a), Non-invasive diagnostic investigation rate in subsequent screening (Id7b).	
Revision history	Introduction: 6.03.2017.	
Id8	**Invasive diagnostic investigation rate**	
Type (N°)	Indicator (Id8)	**KPI: -**
Definition	Number of screen-positive (recalled) screenees undergoing an invasive assessment (additional imaging only) as a rate of all screenees in year X (per 1'000).	
Rationale	Id 8 is a quality indicator that gives information on the risk to have an invasive assessment when participating in screening: to minimise unnecessary invasive procedures is a main objective of a screening programme.	
Calculation	Numerator: Screenees with invasive diagnostic investigations x 1'000 Denominator: Screenees	
Formula	$=\frac{v10}{v6}$x1'000	
Target		
Subdivisions	Invasive diagnostic investigation rate in initial screening (Id8a), Invasive diagnostic investigation rate in subsequent screening (Id8b).	
Revision history	Introduction: 6.03.2017.	
Id9	**False-positive rate**	
Type	Indicator (Id9)	**KPI: -**
Definition	Number of recalled screenees in year X undergoing further diagnostic investigation which do not confirm the presence of a breast cancer (DCIS or invasive) as a rate of all screened women in year X (per 1'000).	
Rationale	Id9 is a quality indicator of the screening programme as it provides feedbacks about the number of women who experienced a short-lasting distress and anxiety that would not have occurred without screening.	
Calculation	Numerator: False positive screenees x 1'000	

	Denominator: Screenees	
Formula	$=\frac{v11}{v6}$x1'000	
Target	None.	
Subdivisions	False-positive rate in initial screening (Id9a), False-positive rate in subsequent screening (Id9b).	
Revision history	Introduction: 6.03.2017.	
Id10	**Breast cancer detection rate**	
Type (N°)	Indicator (Id10)	**KPI: 14**
Definition	Number of screen-positive screenees in whom breast cancer (DCIS or invasive) is confirmed after clinical assessment as a rate of all screened women in year X (per 1'000).	
Rationale	Id6 is an early impact key parameter for the performance of a screening programme. It represents the ability of the screening programme to detect asymptomatic breast cancer and should therefore be higher than the underlying breast cancer incidence.	
Calculation	Numerator: Screenees with a screen-detected breast cancer x 1'000	
	Denominator: Screenees	
Formula	$=\frac{v12}{v6}$x1'000	
Target	Prevalent round: not applicable for Switzerland due to frequent opportunistic screening. Incident round: 1,5x incidence in Switzerland.	
Subdivisions	Breast cancer detected rate in initial screenees (Id6a), Breast cancer detected rate in subsequent screenees (Id6b).	
Revision history	Introduction: 6.03.2017.	
Remarks	- For women with bilateral breast cancers, only the cancer with the worst prognosis should be considered in the analysis. - The breast cancer detection rate will generally be higher for prevalent screening, detecting prevalent cancers, than for subsequent screening. However, women undergoing a previous "opportunistic mammography screening" (i.e. outside the programme) could lower the breast cancer detection rate also in prevalent screening.	
Id11	**Positive predictive value of the screening test (PPV)**	
Type (N°)	Indicator (Id11)	**KPI: -**
Definition	Number of screen-positive screenees with a breast cancer (invasive or DCIS) detected as a proportion (%) of all screen-positive women in year X.	
Rationale	The positive predictive value (PPV) is a quality indicator of the predictive validity of screening: a better performance of screening programmes is achieved with a higher PPV.	
Calculation	Numerator: Screenees with breast cancer x 100	
	Denominator: Screen-positive screenees	

Formula	$=\frac{v12}{v8}$x100 v12/v8!	
Target	None.	
Subdivisions	PPV in initial screening (Id11a), PPV in subsequent screening (Id11b).	
Revision history	Introduction: 6.03.2017.	
Remarks	The initial screen establishes a normal baseline. PPV tends to improve with subsequent screening.	
Id12	**Proportion of DCIS**	
Type (N°)	Indicator (Id12)	**KPI: -**
Definition	Number of screen-detected **ductal carcinoma in situ** (**DCIS*)*** as a proportion of all screen-detected breast cancers (%).	
Rationale	Id12 is a quality indicator. The DCIS is an obligate precursor of invasive disease. The proportion of screen-detected DCIS is a good parameter for assessing the performance of a screening programme (quality indicator). The removal of DCIS, particularly of high-grade type DCIS, could contribute to the long-term mortality reduction. However, a part of the detected DCIS will represent overdiagnosis and lead to overtreatment. DCIS detection is also an indicator of image quality, radiologist prediction and assessment adequacy (EU Standards, p. 185).	
Calculation	Numerator: Screenees with DCIS x 100	
	Denominator: Screenees with breast cancer	
Formula	$=\frac{v14}{v12}$x100	
Target	Initial and subsequent screening: (CH/EU). Acceptable level: 10%; desirable level >15%.	
Subdivisions	Proportion of DCIS at initial screening (Id12a), Proportion of DCIS at subsequent screening (Id12b).	
Revision history	Introduction: 6.03.2017.	
Remarks	With the higher sensitivity, DCIS detection increased overtime. DCIS could be associated with a higher over-diagnosis compared with invasive breast cancer, i.e tumors that would never been discovered without mammography, not representing a life-threatening disease for the women involved.	
Id13	**Proportion of invasive screen-detected breast cancer**	
Type (N°)	Indicator (Id13)	**KPI: 16**
Definition	Number of screen-detected invasive breast cancers as a proportion of all screen-detected breast cancers (%).	
Rationale	Id13 is a quality indicator showing the capacity of the programme in finding invasive cancer.	
Calculation	Numerator: Screenees with invasive breast cancer x 100	
	Denominator: Screenees with breast cancer	
Formula	$=\frac{v15}{v12}$x100	

Target	Initial and subsequent screening: LSC/EU). Acceptable level: 90%; Desirable level 80-90%.	
Subdivisions	Proportion of invasive screen-detected breast cancer at initial screening (Id13a), Proportion of invasive screen-detected breast cancer at subsequent screening (Id13b).	
Revision history	Introduction: 6.03.2017.	
Id14	**Proportion of TNM-Stage II+ breast cancer**	
Type (N°)	Indicator (Id14)	**KPI: 17**
Definition	Number of screen-detected TNM-Stage II+ breast cancer as a proportion of all screen-detected breast cancer (%).	
Rationale	Id14 is a prognostic and early impact indicator. In subsequent screening rounds, the number of Stage II+ cancer should be reduced.	
Calculation	Numerator: Screenees with TNM-Stage II+ x 100	
	Denominator: Screenees with breast cancer	
Formula	$=\frac{v13}{v12}$x100	
Target	Initial screening (CH/EU Standards): Acceptable level: not applicable; Desirable level: <30% Subsequent screening (CH/EU Standards): Acceptable level: ≤25%; Desirable level: <25%	
Subdivisions	TNM-Stage II+ breast cancer at initial screening (Id14a), TNM-Stage II+ breast cancer at subsequent screening (Id14b).	
Revision history	Introduction 6.03.2017.	
Id15	**Proportion of node-negative invasive breast cancer**	
Type (N°)	Indicator (Id15)	**KPI: 18**
Definition	Number of screen-detected node-negative breast invasive cancers as a proportion of all screen-detected invasive breast cancers (%).	
Rationale	Id15 is a prognostic and early impact indicator: to maximize the detection of breast cancer before it spreads to the lymph nodes is a main objective of the screening.	
Calculation	Numerator: Screenees with node negative invasive breast cancer x 100	
	Denominator: Screenees with invasive breast cancer	
Formula	$=\frac{v16}{v15}$x100	
Target	Initial screening (CH/EU Standards): Acceptable level: not applicable; Desirable level: >70% Subsequent screening (CH/EU): Acceptable level: 75%; Desirable level: >75%	
Subdivisions	Proportion of node negative screen-detected cancer at initial screening (Id15a), Proportion of node negative screen-detected cancer at subsequent screening (Id15b). See also 5c.	

Revision history	Introduction 6.03.2017.	
Id16	**Proportion of invasive breast cancer ≤ 10 mm in size**	
Type (N°)	Indicator (Id16)	**KPI: 19**
Definition	Number of invasive cancers ≤10 of size as a proportion of screen-detected invasive breast cancers (%).	
Rationale	Id16 is a prognostic and early impact indicator: to maximize the number of small invasive breast cancers in a pre-clinical stage is a main objective of the screening.	
Calculation	Numerator: Screenees with invasive breast cancer smaller or equal to 10 mm x 100	
	Denominator: Screenees with invasive breast cancer	
Formula	$=\frac{v17}{v15}$x100	
Target	Initial screening (CH/EU Standards): Acceptable level: not applicable; Desirable level: ≥25% Subsequent screening (CH/EU Standards): Acceptable level: ≥25%; Desirable level: ≥30%	
Subdivisions	Invasive breast cancer ≤10 mm at initial screening (Id16a), Invasive breast cancer ≤10 mm subsequent screening (Id16b). See also 5c.	
Revision history	Introduction 6.03.2017.	
Id17	**Proportion of invasive breast cancer < 15 mm in size**	
Type (N°)	Indicator (Id17)	**KPI: 20**
Definition	Number of screen-detected invasive breast cancers with a size <15 mm as a proportion of all screen-detected invasive breast cancers (%).	
Rationale	Id17 is a prognostic and early impact indicator: to maximize the number of small invasive breast cancers is a main objective of screening.	
Calculation	Numerator: Screenees with invasive breast cancer smaller than 15 mm x100	
	Denominator: Screenees with invasive breast cancer	
Formula	$=\frac{v18}{v15}$x100	
Target	Initial screening and Subsequent screening (CH/EU Standards): Acceptable level: 50%; Desirable level: >50%.	
Subdivisions	Invasive breast cancer **<**15 mm at initial screening (Id17a), Invasive breast cancer **<**15 mm subsequent screening (Id17b). See also 5c.	
Revision history	Introduction: 6.03.2017.	

Annex II: Methodology

i. Screening processes and terminology[15]

Only **asymptomatic, average-risk women** (who do not report symptoms and appear without signs of breast cancer at screening) should participate in an organized screening programme. Symptomatic women are provided with specially tailored health services.

At the national level, the "woman" is considered as the basic unit during a screening cycle for all calculations (one screening examination, one recall/referral and one screening result, true- or false-positive, per woman).

Not the whole **target population** (women from 50 to 69 (or 74) years old, living in the programme area) is invited at the same time. Given the two-year interval, only approx. half of the targeted women at the beginning of a calendar year are invited in year X; the other half will be invited in calendar year X+1. **Eligible women** who did not receive any invitation but have fixed an appointment by themselves are called "**self-invited" women**.

Id1-5 are computed with the variables V1-5, being a part of the "Invitation group" (women invited form January 1st to December 31st of year X). Among invited, some have participated during this period. They are called "**Participants**".

Id 6-17 are computed with the variables V6-18, being a part of the "Screenee group" (women who took an exam from January 1st to December 31st of year X, irrespective of the year of invitation, are called "**Screenees**").

The **screen-negative screenees** do not need further assessment. They will be re-invited in the next screening round as long they then belong to the target population. All women with a mammographic lesion at the screening mammography (**screen-positive screenees**) are **recalled for further assessment**[16]. In some of them breast cancer will be confirmed.

When the screen-positive mammography does not result in the diagnosis of a malignancy after clinical assessment the case is called "**false-positive"**. These women will be re-invited in the next screening round as long they then belong to the target population.

In case of multiple breast malignancies, the tumour of worst prognosis is taken into account. "Worst" is defined by the following order from a less to a more favourable prognosis: Distant metastases (M1) > lymph node positive tumour (N+ > N-) > extent tumour size (T2 > T1 etc.) > invasive carcinoma (> ductal carcinoma in situ). All the definitions are defined according to AJCC Cancer Staging Manual, 8th Edition.

[15] Only Swiss specific definitions are provided. Other terms are defined in IARC Handbook of Cancer Prevention Volume 7, 2002. https://www.iarc.fr/en/publications/pdfs-online/prev/handbook7/Handbook7_Breast-11.pdf

[16] In women screened in year X, the further assessment may take place in year X+n but it still belongs to the screening outcome of the year X.

A woman can, in principle, participate up to 24 months until her next invitation. This will delay the extraction of the monitoring data. Therefore, participation is limited to a 12-month period after receipt of the individual invitation for the calculation of the participation rate.

ii. Age definition

Attention must be paid to a consistent age definition across all steps of the screening process. Age at invitation is used for participation indicators (participants). Age at screening is used for all performance indicators (screenees). The women aged 50-74 can be invited.
In both groups, participants or screenees, the age calculation is based on the birth year only and does therefore not represent the real age at the event date.

iii. Data Sources

The demographic data needed to estimate the extent of the target population were provided by the Federal Statistical Office (https://www.bfs.admin.ch/bfs/fr/home/statistiques/population/effectif-evolution.assetdetail.5887433.html).

All primary data are extracted from MC-SIS as described in Chapter 4.

iv. Scope

All organised screening programmes having achieved a first round in the monitoring period of interest provide data for the report. Only full years of activity are considered (e.g. starting years or years with interruption of a programme are excluded).

v. Data stratification

The results are stratified according to first participation in screening (prevalent round) and successive participations (incident round). Since the evolution of lesions detected on prevalent mammograms cannot be compared with the previous images, the prevalent participants are more frequently recalled for additional examinations. The rate of false-positive results is also higher in this population.

Results are stratified by age, when needed.

vi. Screen-detected and interval breast cancer

As breast is a paired organ, cancer can occur in both breasts, at the same (“synchronous”) or at a different (“metachronous”) moment. As screening aims at the improvement of health and the prevention of breast cancer death, it makes more sense to consider women as the basic unit for monitoring and (epidemiologic) evaluation rather than breasts. This means, that there is just one mammography screening examination irrespective of the number of mammograms taken, one referral recommendation irrespective of the number of unclear suspect lesions, one breast cancer detected by screening, irrespective if morphologically more than one breast neoplasm has been diagnosed during the assessment of a screen-positive woman, and one interval cancer. In case of synchronous breast cancer, the most advanced cancer (worse prognosis) should be considered.

This means that a recall (or a referral) followed by a diagnostic assessment that results in a breast cancer diagnosis will be regarded in epidemiological sense as screen-detected breast cancer (true-positive screening result). This is irrespective whether:

- the cancer is located in the same breast and/or at the same place as the suspect mammography lesion;

- a double-sided recall results in only one cancer diagnosis; or whether
- a one-sided recall results in a double-sided breast-cancer.

The pragmatical reason is that without the recall due to a screening examination the breast cancer would not have been diagnosed at that moment.

For radiological evaluation, however, the classification of screen-detected and interval breast cancers depends on the identical or non-identical laterality of the suspect mammography lesion and the cancer.

In cases of an initially undecided diagnostic assessment leading to one or more repeated assessments several months later and finally resulting in a breast cancer diagnosis, it is recommended to regard such a cancer as screen-detected, if the diagnosis takes place within one year after the screening examination, and as interval cancer after a period longer than one year. A negative initial diagnostic assessment (regarding the suspect lesion as benign) means automatically a false-positive screening result. Any later diagnosed breast cancer (not due to a following screening examination) has to be regarded as an interval cancer.

Annex III: Data validation protocol

Reference persons: Jean-Luc Bulliard and Christian Herrmann

Preliminary validation checks:

a. Reads all variables from each csv file
b. Preliminary rough checks on numbers and codes
c. Preliminary filter of relevant variables (Moni, Eval, etc)
d. Check max grouping of lesions (nbregr), anomaly (acnbr) and lesions (nbles)
e. Link some tables (Adresse and Dossiers, etc.)

Validation tests for eligibility:

a. Table Dossiers: - remove «clandestines»
b. Table Adresse: - keep only records with OFS residence code (n=0 up to 649 (FR))
c. Table Chemin:
   - Reads all the relevant chronological events and checks errors
   - Treat all voluntary errors (trick to unblock a dossier: round starting with REFUS_DEF)
   - Delete unnecessary or erroneous events (ex. CHGVT_VG followed by INVIT same day in TG (n>10000)
   - Delete dossier with a single event (creation_dossier)
   - Treat one-event round (RENVOI, CHGT_VAGUE, etc.)
   - Groups events named differently (ex: invitation, ca. 15 names)
   - Treat events inducing unnecessary change of rounds
   - Correct bugs in round incrementation ! (ex: chgt_vague in last event of a round should have the next round number as its first event)
   - Make some pre-migration events compatible with post-migration ones (ex: Malade => definitive or temporary)
   - Treat different use of the same event par different programs (ex: Exclusion, sordep, BEJUNE, FR, VD all differ)
   - Delete “invitation” as last event of a round when the next starts the same day by an invitation (very common bug)
   - Groups unique events per round when not unique (refus, malade) according to date
   - Creates a round counter after cleaning
   - Treat new round after a final/blocking event in prior round (death, cancer, final refusal, definitive exclusion)
   - Treat event of ineligibility when mammo done subsequently
   - Treat incompatible events (ex: cancer_avant_dep and cancer_intervalle)
   - Treat mammography done in ineligible subjects (prior cancer, prosthesis)

Other important computing validations:

a. Groups additional investigation per type (clin, adim, cyp, mbi, biop)
b. Sorts lesions and investigations from most recent to oldest
c. Recodes exams’ result from least to most significant (“probant”)
d. Identifies the most recent exam of each type and the most significant result for each type
e. Aggregates investigation per round
f. Built various aggregate variables at the woman’s level: breast density, laterality, type of lesions (MIC, OPAC; etc), treatment
g. Creates various indicators (invasiveness of investigation)
h. Identifies CLIS tumours

Specific validation tests:

a. Discards records out of screening area
b. Converts pre-migration (2008) codes to MultiFondacs codes (var: lectcr, concl)
c. Standardise prosthesis and breast density codes across programs and time (pre/post-2008 migration)
d. Codes mammo technology (analogic vs digital, whenever possible)
e. Recodes unknow stage (pT) when 5th digit malignancy and size allow it
f. Ranks multiple lesions from the most to least severe ones (with associated variables permuted)
g. Recodes final diagnosis as cancer when cancer morphology known and final diagnosis coded as ongoing
h. Lists negative mammography results with final diagnosis as cancer
i. Lists cancer cases without malignancy or with benign cancer code