GISCi
Gruppo Italiano Screening del Cervicocarcinoma
Convegno Nazionale GISCi
MILANO 26-27 OTTOBRE 2023

WORKSHOP CONGIUNTO ONS - GISCI (ORGANIZZAZIONE)

Nuovo sistema informativo europeo e contributi informativi richiesti per lo screening cervicale

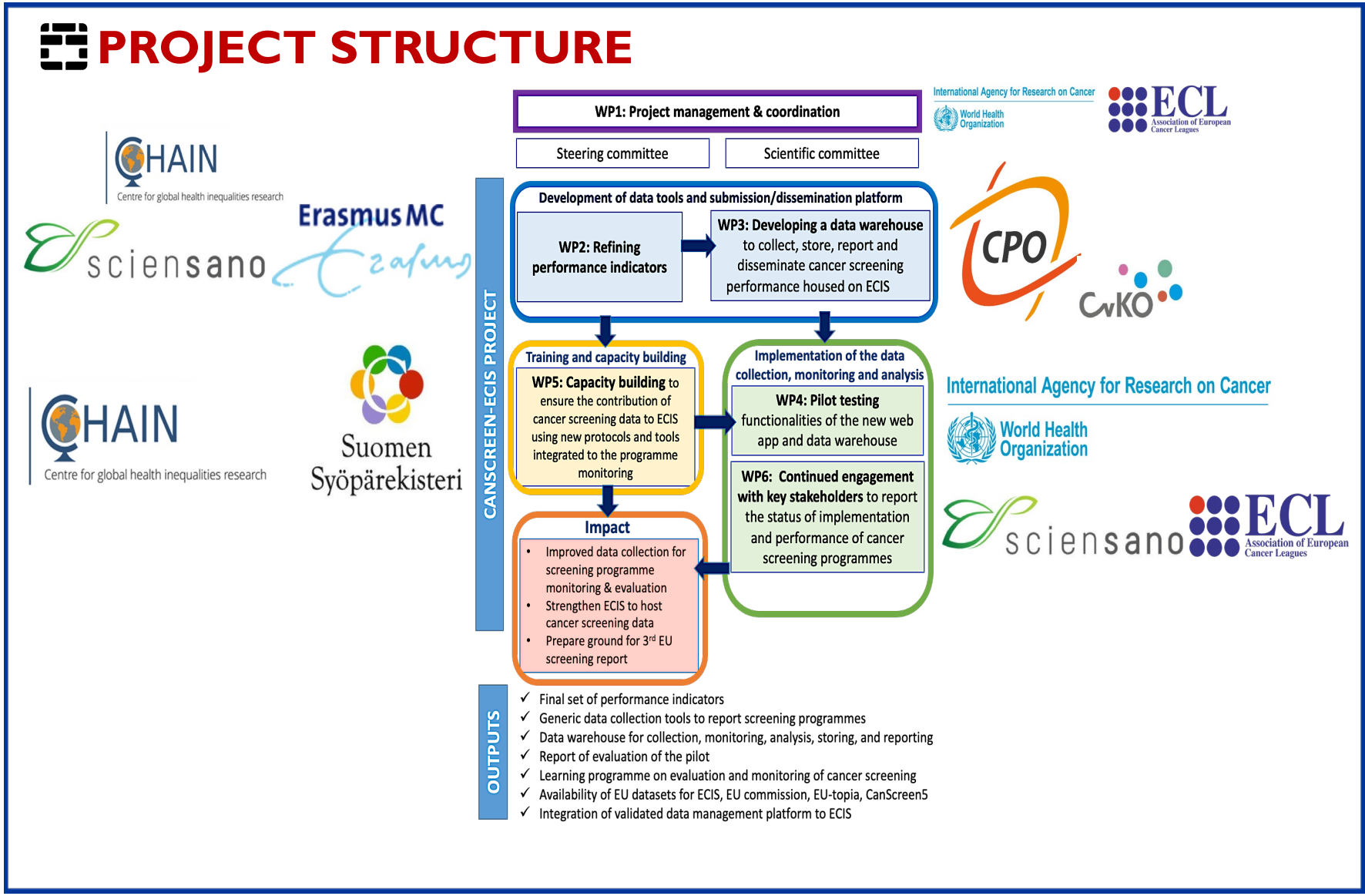
P. Armaroli

CPO Piemonte-AOU Città della Salute e della Scienza di Torino

Il Centro comune di ricerca (JRC) della Commissione europea, in stretta collaborazione con la Direzione Generale della Salute e della Sicurezza alimentare (DG-SANTE), ha sviluppato un "**Sistema europeo di informazione sul cancro**" (ECIS).

ECIS raccoglie al momento i dati della rete dei registri tumori

Il progetto **CanScreen-ECIS** mira a **integrare in ECIS** la raccolta dei **dati di attività** e il calcolo degli **indicatori di qualità** delle prestazioni dai **programmi di screening** del cancro nei paesi europei, con l'obiettivo finale di **diffondere** le informazioni relative alla **qualità** e ai **risultati** dei programmi e consentire ai programmi di **valutare le proprie prestazioni su base continuativa**.



CanScreen-ECIS has received funding from the EU4Health programme under Grant Agreement No 101056947

La raccolta di dati più completa fino ad oggi per stimare un numero critico di indicatori di prestazione nell'Unione europea è stato il **Secondo report europeo sullo screening del cancro** (RSUE) pubblicato nel 2017, attraverso un progetto coordinato dall'Agenzia internazionale per la ricerca sul cancro (IARC), Centro di Riferimento per l'Epidemiologia e la Prevenzione Oncologica (CPO) e il Finnish Cancer Registry

Il RSUE ha raccolto per la prima volta **dati quantitativi**, introducendo tecniche standardizzate per calcolare gli indicatori di prestazione in modo che tali indicatori fossero **comparabili tra paesi/programmi**.

Il rapporto ha mostrato un **aumento sostanziale** tra il 2007 e il 2016 della percentuale di abitanti degli Stati membri dell'UE **invitati** per lo screening del cancro al seno, alla cervice e al colon-retto. Allo stesso tempo, il rapporto ha evidenziato la significativa **eterogeneità nell'organizzazione e nella qualità dei programmi di screening in corso** (Senore 2019; Armaroli 2020). I **test opportunistici sono ancora molto comuni**, soprattutto nello screening del cancro della cervice. Una raccomandazione fondamentale dell'RSUE era che il **monitoraggio dello screening dovesse essere continuo con relazioni pubblicate a intervalli regolari**. Inoltre, gli autori hanno raccomandato il **perfezionamento di alcuni indicatori di prestazione per confrontare meglio le prestazioni in diversi contesti**.

Cancer Screening in the European Union (2017)

Report on the implementation of the Council Recommendation on cancer screening

Health and Food Safety

Table 4.7. Cervical cancer screening programmes in the EU

Key screening policy features in the responding member

Member state or region [2]	Women invited [1]	Age range (years)
Belgium	No opportunistic	25-64
Belgium Flemish region	No opportunistic	25-64
Croatia		
Czech Republic		
Denmark		
Estonia		
Finland		
France		
France 13 depts.		
Hungary		
Ireland		
Italy		
Latvia		

Table 3.5. Cervical cancer screening programmes in European Union Member States 2016

30-59-year-old women in estimated national target populations[1]

Population estimates by screening test, programme type and country implementation status

Screening	Population-based programmes	Non-population-based programmes	No programme or excluded population[3]		Total	
			e to	women (x1,000)	member states	women (x1,000)
					1	1,859

Table 4.8. Cervical cancer screening programmes in the EU

Invitation coverage (on annual population) (%)

Numerator (N) = Individuals personally invite
Denominator (D) = EUROSTAT population obt
that age.
For example:
A) Women 25-64 years screened every 3 year
B) Women 25-49 years screened every 3 year

	30-5
	N
Belgium	257,259
Belgium Flemish region	257,259

Table 4.10. Cervical cancer screening programmes in the EU

Examination coverage:

Proportion (%) of the target population tested in the index year

Numerator (N) = Individuals screened in the year

Denominator (D) = EUROSTAT population obtained from the age-specific female population living in the area divided by the screening interval for that age.

For example:

ominator is female $Pop_{25-64} \div 3$

60-64 screened every 5 years: denominator = Pop25-49÷3 + Pop50-64÷5

years		All ages			Notes
D	%	N	D	%	
436,976	41.8%	232,880	564,373	41.3%	*1*
946,590	55.2%	2,127,985	4,317,116	49.3%	*1*

Table 4.13.1. Cervical cancer screening programmes in the EU:

Other performance indicators

Colposcopy referral (%)

Numerator (N) = Women referred to colposcopy
Denominator (D) = Women with information available on colpo

	30-59 years		
	N	D	%
Czech Republic	15,293	1,239,162	1.2%
Denmark	9,302	304,796	3.1%
Finland	1,376	143,865	1.0%
Hungary			
Italy	27,634	1,081,153	2.6%
Netherlands			
Poland			
Portugal Azores	90	4,253	2.1%
Slovenia	998	113,736	0.9%
Sweden	12,387	329,022	3.8%
UK England			
UK Wales	3,863	142,604	2.7%
Europe	**70,943**	**3,358,591**	**2.1%**

Notes

1) Includes referrals for clinical reasons and HPV.
2) Colposcopy substantially part of screening primary visit.
3) Referral inferred from cytological classification.
4) Women referred not reported by age. Assuming all referred a
5) Women referred because of symptoms excluded.
6) If programme covers only some regions, just these areas are

9) The "All ages" coverage is 4
10) If programme covers only

Table 4.13.3. Cervical cancer screening programmes in the EU:

Other performance indicators

Detection rate of CIN2+ (/1,000)

Numerator (N) = All histological diagnoses CIN2+
Denominator (D) = Individuals screened in the year

	30-59 years			All ages			Notes
	N	D	‰	N	D	‰	
Czech Republic	2,515	1,239,162	2.0	4,282	2,127,985	2.0	*1*
Denmark	3,079	304,796	10.1	5,136	402,561	12.8	*2*
Finland	424	143,913	2.9	445	174,482	2.6	*3*
Hungary							
Italy	4,422	1,052,764	4.2	4,836	1,399,629	3.5	*4*
Netherlands				3,822	504,338	7.6	
Poland				723	694,719	1.0	*5*
Portugal Azores	17	4,253	4.0	20	5,440	3.7	*6*
Slovenia	514	113,736	4.5	719	164,364	4.4	
Sweden	2,222	329,022	6.8	4,277	447,977	9.5	
UK Wales	1,337	142,604	9.4	2,294	186,430	12.3	*7*
Europe	**14,530**	**3,330,250**	**4.4**	**26,554**	**6,107,925**	**4.3**	*8*

Notes

1) Data providers suggest histology registration is largely incomplete leading to large underestimation.
2) Historically very high DR. High HPV prevalence.
3) Competitive detection by opportunistic screening relevant.
4) Some colposcopies done outside organised screning, plausibly relevant only in southern regions.
5) Many colposcopies done outside organised programme.
6) Some colposcopies done outside the programme.The main reason is large delay in reporting.
7) Recent start.
8) If programme covers only some regions, just these areas are considered.

Un altro progetto in cui sono stati raccolti indicatori di performance dello screening del cancro in Europa è **EU-TOPIA** (Towards Improved Screening for Breast, Cervical and Colorectal Cancer in all of Europe)) (EU-TOPIA, 2015-2020) EUTOPIA East 2021-2026).

Il progetto EU-TOPIA mirava a **valutare e quantificare sistematicamente i danni e i benefici d**ello screening del cancro al seno, alla cervice e al colon-retto nei paesi europei.

Gli indicatori di prestazione raccolti dai paesi partecipanti, visualizzati e analizzati in uno **strumento di monitoraggio online** (www.eutopia.cpo.it), sono stati utilizzati come input per **modelli innovativi di microsimulazione** della **storia naturale** dei tre tumori per valutare danni, benefici e rapporto costo-efficacia dello screening del cancro (Gini et al, 2021). Un vantaggio dell'utilizzo di questi modelli di microsimulazione è che non solo è possibile valutare la situazione attuale, ma si possono valutare anche molti **scenari alternativi per quantificare gli effetti delle modifiche al programma** sui danni, sui benefici e sul rapporto costo-efficacia dello screening (Jansen et al. , 2021; Zielonke et al, 2021).

Gli indicatori di prestazione definiti e utilizzati da RSUE e EU-TOPIA saranno **perfezionati e nuovi indicatori** sono stati proposti per:

1) consentire il **confronto tra le diverse modalità organizzative** dei programmi di screening;

2)consentire la raccolta di dati sulle sperimentazioni esterne ai programmi;

3) consentire al sistema di monitoraggio di **identificare e quantificare le informazioni sulle disuguaglianze**;

4) coprire **nuovi approcci di screening** e potenziali nuove sedi di cancro per il futuro.

Gli strumenti di raccolta dati per i programmi di screening per i tumori al seno, alla cervice e al colon-retto sono stati progettati in linea con i nuovi indicatori.

La **raccolta sistematica dei dati** per misurare gli indicatori è una **componente chiave della valutazione del programma di screening**.

Pertanto, per la valutazione del programma, è essenziale lo sviluppo di **sistemi completi che garantiscano una documentazione tempestiva e accurata** dei processi di screening, sulla base del monitoraggio sistematico dei dati relativi alla performance.

L'acquisizione di informazioni di alta qualità attraverso una compilazione accurata e un reporting standardizzato dei risultati rappresenta un passo cruciale nel processo di garanzia della qualità.

CanScreen-ECIS ha definito un insieme **di indicatori prioritari e** ha progettato **strumenti di raccolta dati adeguati** che tutti i programmi di screening saranno in grado di utilizzare per raccogliere **dati quantitativi di monitoraggio per misurare gli indicatori di prestazione** stratificati per vari parametri programmatici e demografici

La raccolta dei dati deve basarsi sulle **attività di monitoraggio di routine già in corso** a livello regionale o nazionale in modo che non sia necessario modificare il quadro esistente per la gestione e la protezione dei dati.

Per garantire la comparabilità dei dati raccolti, ciascun programma sarà tenuto a rispettare un **formato standard** per la raccolta dei dati sulle attività di screening. Il rispetto di tale standard potrebbe richiedere un **aggiornamento delle procedure abitualmente** adottate per la rendicontazione nazionale e/o subnazionale.

Parallelamente è necessario **rafforzare il sistema informativo sullo screening**.

Attraverso CanScreen-ECIS verrà creato un **data warehouse** alimentato dai dati raccolti e inviati dai programmi di screening utilizzando strumenti di raccolta dati standardizzati. Questo data warehouse basato sul web **non include al momento dati personali** poiché verranno raccolti solo **dati aggregati** per ciascun sito tumorale, stratificati in base a determinanti rilevanti

Trattandosi di dati aggregati non si applicano le regole del GDPR

CanScreen-ECIS mira a **incorporare uno strumento di analisi dei dati** nel data warehouse.

Utilizzando formule standardizzate comuni per l'analisi dei dati quantitativi aggregati forniti da ciascun programma, lo strumento dovrebbe consentire la derivazione di indicatori standardizzati di prestazione dello screening di qualità (stratificati per età, sesso, storia di screening, metodo di screening e stato socioeconomico), consentendo il **confronto dei risultati** dei programmi tra paesi e regioni.

CanScreen-ECIS mira a sviluppare un'applicazione web di esplorazione dei dati che consenta di **visualizzare i** risultati delle analisi predefinite attraverso **mappe interattive, grafici e tabelle**

Verrà effettuata **una fase pilota** delle funzionalità raccogliendo set di dati aggregati sullo screening del cancro al seno, alla cervice e al colon-retto da paesi selezionati. Sulla base di una valutazione obiettiva del progetto pilota e del **feedback** ricevuto da tutte le parti interessate, sarà effettuato un **perfezionamento** finale dei prodotti web prima dell'integrazione in ECIS.

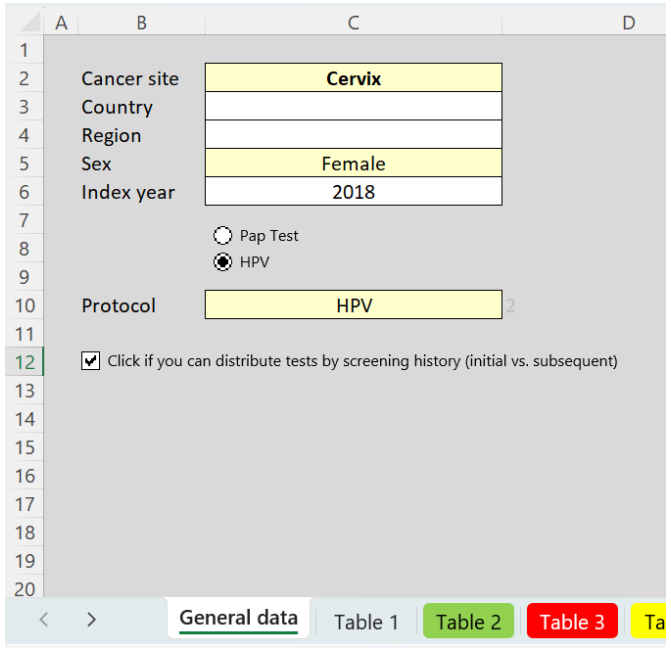
Verrà sostenuto inoltre lo sviluppo delle risorse per lo sviluppo di capacità e un’ampia diffusione dei risultati del progetto

CanScreen ECIS

Cervical cancer screening

Paola Armaroli, CPO

General data



Cancer site: **Cervix** (Fixed value)

Country: Specify the country you are referring to.

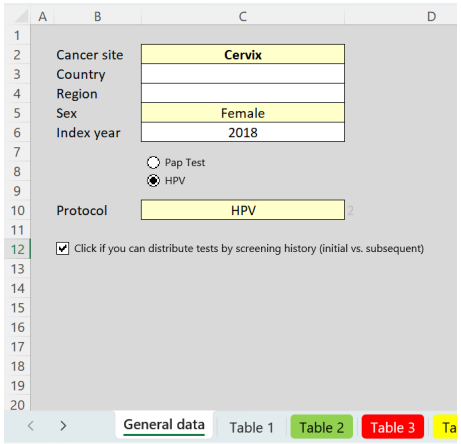
Region: If data refer to a region, please specify here its name(s).

Sex: **Female** (Fixed value.)

Index year: Specify the index year the tables 1 to 9 refer to.

Click the *checkbox* if you can distribute tests by screening history (initial vs. subsequent)

Protocol



Options for primary screening tests (first test being performed for screening):

Pap-test: All women are tested just for cytology. HPV may be performed, but only to triage cytology-positive women.

HPV-test: All women are tested just for HPV. Cytology may be performed but only to triage HPV-positive women.

If the program is using both tests, please, fill two separate series/files of tables (two data templates) referring in each set to the population targeted for each test (for example: Pap-test for women aged 25 to 29 and HPV-test for women 30 and over)

Table 1. Population

Table 1. Population

	A1	A2	A1 : A2	A3
	Target population	Screening intervals in years	Annual target population	Program annual target population
Up to 19			0	
20-24			0	
25-29	22361		0	
30-34	25812		0	
35-39	28525		0	
40-44	34740		0	
45-49	36890		0	
50-54	35406		0	
55-59	31108		0	
60-64	28119		0	
65-69			0	
70-74			0	
75-79			0	
Unknown			0	78113
Total	242961		0	78113

Notes: * Use this box to specify the adopted exclusion criteria (before invitation) and add comments on your data collection.

A1	Target population	Total number of age-eligible women obtained from official statistics (EUROSTAT) irrespective of the screening interval
A2	Screening interval in years	Interval (in years) between routine screens decided upon in each screening programme dependent on screening policy.
A3	Program annual target population (eligibility criteria of the program)	Total number of women targeted by the program after having applied the exclusion criteria (exclusions before invitation in a program that invites all eligible women) defined by the local protocol

Table 1. Population

Critical issues, remarks

Progressive introduction of HPV test as primary screening test, both protocols are currently adopted in the same age groups.

If the case the indication is to collect data in two different files for women invited to HPV test and to Pap test in each age class.

Table 2. Invitations and tests by screening history

Table 2. Invitations and tests by screening history

	B1	B2	B3	Individuals screened of invited in 2018		B4=B2	B4o	B4a	B4b
	Individuals personally invited in 2018	Individuals screened of invited in 2018	Individuals screened in 2018 (following invitation or without invitation but within program)	B4a Initial screening	B4b Subsequent screening	Unknown	Total	Outside-program testing		
Up to 19						0	0		0	0
20-24	2	1		1	0	0	1		1	0
25-29	22	7		7	0	0	7		7	0
30-34	7636	3292		3252	7	33	3292		3252	7
35-39	8055	3544		3454	32	58	3544		3454	32
40-44	10411	4743		3391	1295	57	4743		3391	1295
45-49	11558	5301		4056	1190	55	5301		4056	1190
50-54	11629	5269		3193	2047	29	5269		3193	2047
55-59	9205	3994		2787	1202	5	3994		2787	1202
60-64	8265	3101		1648	1444	9	3101		1648	1444
65-69	192	88		73	15	0	88		73	15
70-74						0	0		0	0
75-79						0	0		0	0
Unknown						0	0		0	0
Total	66975	29340	0	21862	7232	246	29340	0	21862	7232

All the following tables will focus on invitation cohort (organized screening activity)

Columns B1-B4b are requested only for “Population based” screening.
Columns B4a and B4b appear when the box “initial vs. subsequent” is ticked at the General data sheet.
The classification “Population based screening” applies to programmes where individual invitations are sent to all eligible women, or only to women who have not undergone a screening test by their own initiative. In this latter case (‘sorting out strategy’), the program has access to the information, which is necessary to classify all age-eligible women based on their screening status to plan and manage the invitation process.

Table 2. Invitations and tests by screening history

B1	Individuals personally invited in index year (stratified by AGE AT INVITATION)	Requested only for "population based screening", it includes all **personally invited women** (not counting reminders or returned letters) in the reference period for the data collection. Please indicate the number of women invited from January 1st to December 31st of the index year. Do not include invitations to intermediate tests (for example: HPV tests repeated at short interval following a positive screening result and a negative triage) in this column.
B2	Individuals screened of invited in index year (stratified by AGE AT INVITATION)	Requested only for "population based screening", it is a subset of the women-invited-in-index-year who received a test – counting any test performed up to June of the following year (**Invitation cohort**). Do not include tests performed at short interval (for example HPV tests performed following referral for early rescreen of women with a positive screening result and a negative triage test) in this column.
B3	Individuals screened in index year (stratified by AGE AT SCREENING)	Requested only for "population based screening". Women who had a test in index year following an invitation (regardless of when invited), or who performed a test following self-referral in the same index year (**examination cohort**). If a program is inviting only women who are not covered, women counted in this column should include both those performed following the invitation and those who have performed the exams following self-referral. Do not include tests performed at short interval (for example HPV tests performed following referral for early rescreen of women with a positive screening result and a negative triage test) in this column.

Table 2. Invitations and tests by screening history

If any information is collected in column B3, all the following tables collecting data about screening outcomes will focus on people examined in the reference year (**examination cohort**) and the number of tests to be stratified are those in individuals screened in index year.

If no information is collected there, all the following tables collecting data about screening outcomes will focus on **invitation cohort** (i.e. people invited in the reference year who had the proposed test by the end of June of the year following the reference year) and the number of tests to be stratified are those in individuals screened of invited in index year.

The **examination cohort** (column B3) includes both subjects performing a screening exam following an invitation and those performing the test on their own initiative in a certain year. This allows collecting complete information also from countries inviting only subjects who are not covered by spontaneous activity.

Moreover, complete data about the results of the screening process (up to the final diagnosis following assessment) might be available sooner when focusing on this cohort, as compared to what observed in an invitation cohort (subjects performing the test up to the end of June of the year following the reference year for invitation). In this latter case, it might take two years (following the reference year) to get complete information about the screening outcomes of all people responding to the invitation.

Table 2. Invitations and tests by screening history

Outside program testing or non-population based screening, **relies on early detection of disease in people who perform the exams as a** result of either a recommendation made by a health-care provider during a medical consultation usually for symptoms, or self-referral of individuals (eventually reacting to media campaigns), **outside an established protocol** (i.e. no control on the screening interval, or on the age range).

If values are entered in column B4o and no data is entered in columns B2 and B3, then all the subsequent tables (from table 4 to the last one) will collect data about 'Outside program testing' and the tool wil change all labels accordingly.

If data are provided for tables B2 and/or B3 (i.e activity within the population based programs) and data are also entered in column B4o (i.e information about exams performed outside the population-based screening setting in the index year is provided), the following tables will collect data about outcomes of exams performed only within the population based program.

The information collected in column B4o should refer to a distinct set of subjects as compared to those considered in columns B2, B3 / B4 who performed the test (either following a personal invitation or through self-initiative) within the program.

Table 3. Invitations and tests by screening history (initial or subsequent screening)

C1-C4	Women personally invited in index year	It includes all personally invited women (not counting reminders or returned letters) in the period to which data refer. C1: women receiving their first invitation in the programme C2: women invited in the reference year who had already been invited in previous screening rounds C3 (sub-set of C2): women invited in the reference year who had been invited in previous screening rounds and attended screening after **the last invitation** C4 (sub-set of C2): women invited in the reference year who had been invited in previous screening rounds but did not attend the last invitation Please indicate the number of women invited from January 1st to December 31st of the index year. Do not include invitations to intermediate mammograms (short term recalls) in these columns.
C5-C8	Women screened of invited in index year	It is a **subset of the women-invited-in-index-year (C1) who received a test** – counting any test performed up to June of the following year (Invitation cohort). It is also acceptable, assuming steady state, to estimate this number using the number of attenders in the index year - regardless of their invitation date (examination cohort). Do not include tests referring to intermediate mammograms (short term recalls) in these columns. C5: women receiving their test for the first time in the programme C6: women who had already received previous test in the programme C7 (sub-set of C6): women who had received previous tests in the programme after being invited in the previous round C8 (sub-set of C6): women had not attended in the previous round (i.e. not receiving the test in spite of being invited.

Table 3. Invitations and tests by screening history (initial or subsequent screening)

The aim of this table is to collect some basic information about patterns of participation. The response rate to the initial invitation in the program is predictive of the probability to attend also in subsequent rounds. Similarly, the attendance rate of women invited in a subsequent round, who had already participated in the previous one, is predictive of the future response and of the regularity of participation.

Table 4. Test results

Positive: different programs may adopt different criteria for classifying a screening exam as positive.

The detail of the positivity criteria has to be provided in the qualitative questionnaire. Similarly, different programs may adopt different triage methods and different criteria for recommending a triage test.

Triage: the triage method/strategy should be described in the qualitative questionnaire. It is the strategy adopted by the program to manage women with a positive primary screening test result (or with a specific test result: i.e. ASCUs for Pap-smear or specific HPV genotypes, according to local policies) orienting the decision about colposcopy referral, or early rescreen, or routine screening. The information collected in table 4 is referring to the final result of the triage approach adopted by the program (any type of triage)

The table has been designed to collect information about the result of the process (primary test and triage test, when recommended), independent of the criteria adopted to classify the test as positive and of the triage method. If the triage requires the women to come back for an additional sampling (the triage test is not performed on the same sample collected for primary screening), women who do not comply with the referral for triage should be counted in column D4.

In this table, the total number of tests (B4, or B4a and B4b, if the data are stratified by screening history) will be automatically reported from table 2. The total number of tests is to be stratified in the two columns D1 and D2.

Table 4. Test results

Table 4. Test results (including triage outcomes)

		D1	D2	D3	D4	D5		B4
		Pap Test positive directly referred to colposcopy	Referred to colposcopy after abnormal Pap test and positive triage	Referred for early rescreen after negative triage	Pap test positive and triage recommended but not	Pap Test negative	Result unknown	Tests
Initial screening	Up to 19						0	0
	20-24	0				2	0	2
	25-29	174				2311	0	2485
	30-34	8				126	0	134
	35-39	0				7	0	7
	40-44	0				3	0	3
	45-49	1				3	0	4
	50-54	0				3	0	3
	55-59	0				1	0	1
	60-64	0				0	0	0
	65-69	0				0	0	0
	70-74						0	0
	75-79						0	0
	Unknown						0	0
	Total	183	0	0	0	2456	0	2639
Subsequent screening	Up to 19						0	0
	20-24	0				0	0	0
	25-29	32				437	0	469
	30-34	6				110	0	116
	35-39	4				22	0	26
	40-44	0				24	0	24
	45-49	5				43	0	48
	50-54	3				27	0	30
	55-59	0				20	0	20
	60-64	0				9	0	9
	65-69	0				0	0	0
	70-74						0	0
	75-79						0	0
	Unknown						0	0
	Total	50		0	0	692	0	742

Protocol selected:

Pap test

(tick the corresponding box at General data sheet)

D1: Positive Pap test: recommendation for further assessment

D2*: Pap test positive (abnormal) with positive triage test result: referral for further assessment (include all subjects with the indication of a triage test who had a positive result at triage)

D3*: Pap test positive (abnormal) with negative triage: referred for early rescreen (include all subjects with the indication of a triage test who had a negative result at triage)

D4*: Pap test positive and triage recommended but not performed (include all subjects with the indication of a triage test who did not perform (or were not yet invited) the recommended triage test)

D5: Pap-test negative

**Columns D2, D3 and D4 should be filled only by programs adopting a triage*

Table 4. Test results

Table 4. Test results (including triage outcomes)

		D1 HPV + directly referred to colposcopy	D2 HPV + referred to colposcopy after positive triage	D3 HPV+ referred for early rescreen after negative triage	D4 HPV+ and triage recommended but not performed	D5 HPV negative	Result unknown	B4 Tests
Initial screening	Up to 19						0	0
	20-24		0	1		0	0	1
	25-29		0	1		6	0	7
	30-34		128	419		2698	7	3252
	35-39		114	336		3001	3	3454
	40-44		84	283		3019	5	3391
	45-49		85	309		3662	0	4056
	50-54		44	208		2937	4	3193
	55-59		39	178		2570	0	2787
	60-64		18	93		1536	1	1648
	65-69		0	0		73	0	73
	70-74						0	0
	75-79						0	0
	Unknown						0	0
	Total	0	512	1828	0	19502	20	21862
Subsequent screening	Up to 19						0	0
	20-24		0	0		0	0	0
	25-29		0	0		0	0	0
	30-34		1	1		5	0	7
	35-39		11	5		23	-7	32
	40-44		16	90		1186	3	1295
	45-49		22	62		1107	-1	1190
	50-54		26	118		1905	-2	2047
	55-59		6	56		1134	6	1202
	60-64		9	46		1392	-3	1444
	65-69		1	1		14	-1	15
	70-74						0	0
	75-79						0	0
	Unknown						0	0
	Total	0	92	379	0	6766	-5	7232

Protocol selected:

HPV test

(tick the corresponding box at General data sheet)

D1 Positive HPV test immediately referred to colposcopy.
D2 Positive HPV test and positive triage test result. Recommendation is further assessment.
D3 Positive HPV test and negative triage test result: referral for early rescreen
D4 Positive HPV test - triage test recommended but not performed: non-complier
D5 Negative HPV test: Women receiving the recommendation to return to routine primary screening, either following a negative HPV test result or, based on local protocol, following a negative triage test result

Table 4. Test results

Critical issues, remarks

Negative unknown results probably due to compilation for early rescreen results in the following next year after 1year HPV repetition. We check the consistency of data but small discrepancies may occur

Table 5. Early rescreen

Early rescreen: based on the triage result women can be invited to repeat the test following protocols stipulating one or more short-interval follow-up tests.

The interval and the type of test used for rescreening are different across jurisdictions and the details of the adopted strategies should be provided in the qualitative questionnaires.

The table has been designed to collect information about the result of the process (final status at rescreen), independent of the rescreening protocol adopted.

Table 5. Early rescreen

Table 5. Early rescreen

		E1	E2	D3	E3	E4		E1
		Rescreen test performed	Rescreen test not performed (or no	Performance unknown	HPV+ referred for early rescreen after negative	Positive	Negative	Result unknown	Rescreen test performed
Initial screening	Up to 19			0	0			0	0
	20-24	0	1	0	1	0	0	0	0
	25-29	1	0	0	1	0	1	0	1
	30-34	322	97	0	419	176	143	3	322
	35-39	267	69	0	336	148	119	0	267
	40-44	234	49	0	283	120	112	2	234
	45-49	258	51	0	309	114	143	1	258
	50-54	169	39	0	208	88	81	0	169
	55-59	153	25	0	178	83	70	0	153
	60-64	77	16	0	93	42	35	0	77
	65-69	0	0	0	0	0	0	0	0
	70-74			0	0			0	0
	75-79			0	0			0	0
	Unknown			0	0			0	0
	Total	1481	347	0	1828	771	704	6	1481
Subsequent screening	Up to 19			0	0			0	0
	20-24	0	0	0	0	0	0	0	0
	25-29	0	0	0	0	0	0	0	0
	30-34	0	1	0	1	0	0	0	0
	35-39	3	2	0	5	3	0	0	3
	40-44	82	8	0	90	40	42	0	82
	45-49	56	6	0	62	22	34	0	56
	50-54	111	7	0	118	49	62	0	111
	55-59	49	7	0	56	23	26	0	49
	60-64	39	7	0	46	19	20	0	39
	65-69	1	0	0	1	1	0	0	1
	70-74			0	0			0	0
	75-79			0	0			0	0
	Unknown			0	0			0	0
	Total	341	38	0	379	157	184	0	341

Protocol selected:

HPV test

(tick the corresponding box at General data sheet)

In this table, the total number of women referred for early rescreen, automatically reported from table 4, D3, is stratified in the two columns reporting information about rescreen test performance

- **E1** women referred for rescreen who perform the test
- **E2** women referred for rescreen who do not perform the test

The total number of women performing the test recommended for early rescreen (E1) is further stratified in the two columns collecting information about the rescreen test result

- **E3** positive result at early rescreen test
- **E4** negative result at early rescreen test (ideally the final result of the process is the rescreening strategy stipulates more than one test)

* The unknown cases are automatically calculated as the difference between the total (right column) and the sum of the two white columns.

Table 6. Further assessment (colposcopy) participation

Table 6. Colposcopy participation

Immediate referral

		F1 Colposcopy performed	F2 Colposcopy not performed among invited	Unknown whether colposcopy	D1+D2 Referred to colposcopy
Initial screening	Up to 19			0	0
	20-24			0	0
	25-29			0	0
	30-34			128	128
	35-39			114	114
	40-44			84	84
	45-49			85	85
	50-54			44	44
	55-59			39	39
	60-64			18	18
	65-69			0	0
	70-74			0	0
	75-79			0	0
	Unknown	476	36	-512	0
	Total	476	36	0	512
Subsequent screening	Up to 19			0	0
	20-24			0	0
	25-29			0	0
	30-34			1	1
	35-39			11	11
	40-44			16	16
	45-49			22	22
	50-54			26	26
	55-59			6	6
	60-64			9	9
	65-69			1	1
	70-74			0	0
	75-79			0	0
	Unknown	74	12	-86	0
	Total	74	12	6	92

Early rescreen referral

		F3 Colposcopy performed	F4 Colposcopy not performed among invited	Performance unknown	E3 Positive at rescreen
Initial screening	Up to 19			0	0
	20-24			0	0
	25-29			0	0
	30-34			176	176
	35-39			148	148
	40-44			120	120
	45-49			114	114
	50-54			88	88
	55-59			83	83
	60-64			42	42
	65-69			0	0
	70-74			0	0
	75-79			0	0
	Unknown	581	187	-768	0
	Total	581	187	3	771
Subsequent screening	Up to 19			0	0
	20-24			0	0
	25-29			0	0
	30-34			0	0
	35-39			3	3
	40-44			40	40
	45-49			22	22
	50-54			49	49
	55-59			23	23
	60-64			19	19
	65-69			1	1
	70-74			0	0
	75-79			0	0
	Unknown	125	35	-160	0
	Total	125	35	-3	157

Protocol selected:

HPV test

There are two set of tables (by age group, screening history and screening policy): the upper series is for referrals for colposcopy following a positive Pap-test or a positive HPV test with positive triage test result (immediate referral); the lower series is for referrals for colposcopy following a positive early rescreen result (early rescreen referral).
The total to be stratified is the number of colposcopies indicated, automatically reported from table 4 or from table 5.

The information is referring to women screened in the index/reference year (examination cohort), eventually undergoing further assessment in the following year

* The unknown cases are automatically calculated as the difference between the total (right column) and the sum of the two white columns.

Table 7. Pathological outcomes

Critical issues, remarks

Long waiting times, with an appointment fixed but in the long time.

Participation rate might be underestimated if the index year is the previous calendar year (especially for LSIL, low priority for invitation for assessment, if the programs adopts pirority criteria for access to colposcopy)

Table 7. Pathological outcomes

Table 7. Pathological outcomes

		Immediate referral												Adjusted denominator for DR
					Invasive carcinoma									
		G1	G2	G3	G4	G5	G6	G7	G8	G9	G10		F1	B5
		No biopsy performed	Unsatisfactory histology	No CIN/ca detected	Invasive squamous	Micro-invasive squamous	Invasive adenocarcinoma	Other invasive carcinoma	AdenoCa in situ (CGIN)	HSIL	LSIL	Outcome unknown	Colposcopy performed	Screened population for which histological result is
Initial screening	Up to 19											0	0	
	20-24											0	0	
	25-29											0	0	
	30-34											0	0	
	35-39											0	0	
	40-44											0	0	
	45-49											0	0	
	50-54											0	0	
	55-59											0	0	
	60-64											0	0	
	65-69											0	0	
	70-74											0	0	
	75-79											0	0	
	Unknown	77	1	114	4				1	182	95	2	476	
	Total	77	1	114	4	0	0	0	1	182	95	2	476	512
Subsequent screening	Up to 19											0	0	
	20-24											0	0	
	25-29											0	0	
	30-34											0	0	
	35-39											0	0	
	40-44											0	0	
	45-49											0	0	
	50-54											0	0	
	55-59											0	0	
	60-64											0	0	
	65-69											0	0	
	70-74											0	0	
	75-79											0	0	
	Unknown	11	2	26						22	13	0	74	
	Total	11	2	26	0	0	0	0	0	22	13	0	74	92

Protocol selected:

HPV test

There are two set of tables (by age group and screening history): the upper series is for colposcopies performed following a positive Pap-test or a positive HPV test with positive triage test result (immediate referral); the lower series is for colposcopies performed following a positive early rescreen result (Early rescreen referral).

The total to be stratified is the number of colposcopies performed, automatically reported from table 6.

The information is referring to women screened in the index/reference year (examination cohort), eventually undergoing further assessment in the following year

* The unknown cases are automatically calculated as the difference between the total (right column) and the sum of the two white columns.

Table 7. Pathological outcomes

G1	No biopsy performed	
G2	Unsatisfactory histology	This includes inadequate results.
G3	No CIN/Carcinoma detected	Individuals with colposcopy but no biopsy taken or no CIN detected at histology.
G4	Invasive squamous carcinoma	FIGO stage >1A1. Do not include 1A if not further specified if 1A1 or 1A2.
G5	Micro-invasive squamous carcinoma	FIGO stage 1A1. Include 1A if not further specified if 1A1 or 1A2.
G6	Invasive adenocarcinoma	Include adeno-squamous carcinoma.
G7	Other invasive carcinoma	
G8	Adenocarcinoma in situ (CGIN)	
G9	H-SIL	
G10	L-SIL	

Protocol selected:

HPV test

In the group of columns G1 to G10 count each woman only once using the hierarchy of outcomes from most severe to least severe (in practice: G4 to G10)

Table 7. Pathological outcomes

Critical issues, remarks

Data available for invasive lesions as a whole, not available according to Invasive squamous carcinoma, Micro-invasive squamous carcinoma, Invasive adenocarcinoma. In this case the indication is to add a note

Data stratified by age class available for initial and subsequent, not for immediate referral/early rescreen.

Under evaluation the possibility of having for some indicators, tables not stratified (with the options to click the *checkbox* for stratification of tests in each table).

Table 8. Treatment referral and compliance

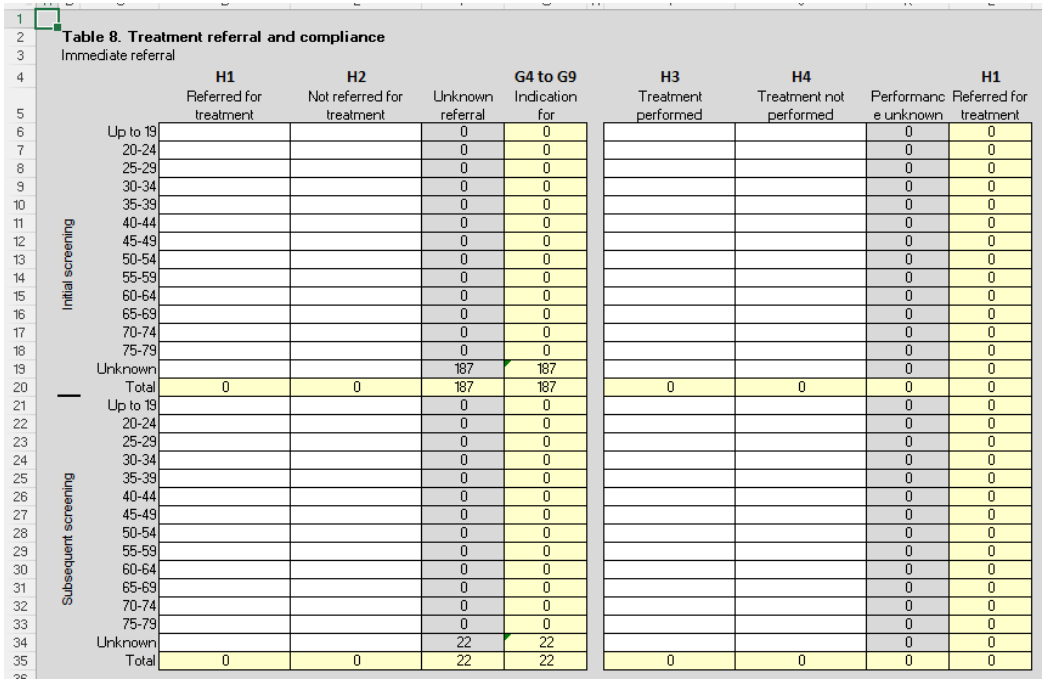
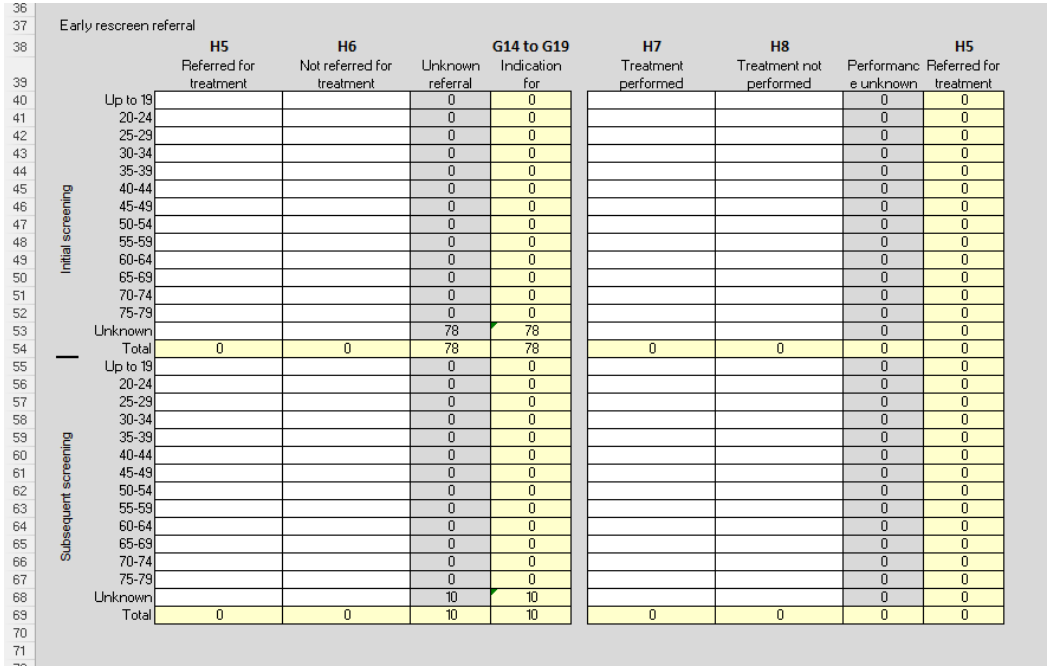


Table 8. Treatment referral and compliance

Immediate referral

		H1 Referred for treatment	H2 Not referred for treatment	Unknown referral	G4 to G9 Indication for	H3 Treatment performed	H4 Treatment not performed	Performance unknown	H1 Referred for treatment
Initial screening	Up to 19			0	0			0	0
	20-24			0	0			0	0
	25-29			0	0			0	0
	30-34			0	0			0	0
	35-39			0	0			0	0
	40-44			0	0			0	0
	45-49			0	0			0	0
	50-54			0	0			0	0
	55-59			0	0			0	0
	60-64			0	0			0	0
	65-69			0	0			0	0
	70-74			0	0			0	0
	75-79			0	0			0	0
	Unknown			187	187			0	0
	Total	0	0	187	187	0	0	0	0
Subsequent screening	Up to 19			0	0			0	0
	20-24			0	0			0	0
	25-29			0	0			0	0
	30-34			0	0			0	0
	35-39			0	0			0	0
	40-44			0	0			0	0
	45-49			0	0			0	0
	50-54			0	0			0	0
	55-59			0	0			0	0
	60-64			0	0			0	0
	65-69			0	0			0	0
	70-74			0	0			0	0
	75-79			0	0			0	0
	Unknown			22	22			0	0
	Total	0	0	22	22	0	0	0	0



Early rescreen referral

		H5 Referred for treatment	H6 Not referred for treatment	Unknown referral	G14 to G19 Indication for	H7 Treatment performed	H8 Treatment not performed	Performance unknown	H5 Referred for treatment
Initial screening	Up to 19			0	0			0	0
	20-24			0	0			0	0
	25-29			0	0			0	0
	30-34			0	0			0	0
	35-39			0	0			0	0
	40-44			0	0			0	0
	45-49			0	0			0	0
	50-54			0	0			0	0
	55-59			0	0			0	0
	60-64			0	0			0	0
	65-69			0	0			0	0
	70-74			0	0			0	0
	75-79			0	0			0	0
	Unknown			78	78			0	0
	Total	0	0	78	78	0	0	0	0
Subsequent screening	Up to 19			0	0			0	0
	20-24			0	0			0	0
	25-29			0	0			0	0
	30-34			0	0			0	0
	35-39			0	0			0	0
	40-44			0	0			0	0
	45-49			0	0			0	0
	50-54			0	0			0	0
	55-59			0	0			0	0
	60-64			0	0			0	0
	65-69			0	0			0	0
	70-74			0	0			0	0
	75-79			0	0			0	0
	Unknown			10	10			0	0
	Total	0	0	10	10	0	0	0	0

In this table, the total to be stratified (in the two columns H1 and H2) is the number “G4 to G9” of women with “HSIL + Invasive cancer” detected at colposcopy automatically reported from table 6.

The information is referring to women screened in the index/reference year (examination cohort), eventually undergoing treatment in the following year

* The unknown cases are automatically calculated as the difference between the total (right column) and the sum of the two white columns.

There are two set of tables (by age group, screening history): the upper series is for colposcopies performed following a positive Pap-test or a positive HPV test with positive triage test result (immediate referral); the lower series is for colposcopies performed following a positive early rescreen result (Early rescreen referral)

H1 Referred for treatment, **H2** Not referred for treatment

Women referred for treatment (H1) are further stratified in two columns (H3 and H4)

H3 Treatment performed, **H4** Treatment not performed

Table 8.Treatment referral and compliance

Critical issues, remarks

Data available for treatment performed according to type of lesion.

Data not stratified.

Table 9. Complications (HSIL treatment)

Table 9. Complications

Immediate referral

		I1 Bleeding / Discharge	I2 Other relevant	I3 No events	Complications unknown	I4 HSIL treatment performed
Initial screening	Up to 19				0	
	20-24				0	
	25-29				0	
	30-34				0	
	35-39				0	
	40-44				0	
	45-49				0	
	50-54				0	
	55-59				0	
	60-64				0	
	65-69				0	
	70-74				0	
	75-79				0	
	Unknown				0	
	Total	0	0	0	0	0
Subsequent screening	Up to 19				0	
	20-24				0	
	25-29				0	
	30-34				0	
	35-39				0	
	40-44				0	
	45-49				0	
	50-54				0	
	55-59				0	
	60-64				0	
	65-69				0	
	70-74				0	
	75-79				0	
	Unknown				0	
	Total	0	0	0	0	0

Early rescreen referral

		I5 Bleeding / Discharge	I6 Other relevant	I7 No events	?	I8 HSIL treatment performed
Initial screening	Up to 19				0	
	20-24				0	
	25-29				0	
	30-34				0	
	35-39				0	
	40-44				0	
	45-49				0	
	50-54				0	
	55-59				0	
	60-64				0	
	65-69				0	
	70-74				0	
	75-79				0	
	Unknown				0	
	Total	0	0	0	0	0
Subsequent screening	Up to 19				0	
	20-24				0	
	25-29				0	
	30-34				0	
	35-39				0	
	40-44				0	
	45-49				0	
	50-54				0	
	55-59				0	
	60-64				0	
	65-69				0	
	70-74				0	
	75-79				0	
	Unknown				0	
	Total	0	0	0	0	0

In this table, the total to be stratified (in the columns I1, I2 and I3) is the number I4 of women who were treated for HSIL (number to be indicated by program).

* The unknown cases are automatically calculated as the difference between the total (right column) and the sum of the two white columns.

I1 Bleeding /discharge (requiring access to the hospital, either admitted or examined in emergency)
I2 Other relevant complications
I3 no events

There are two set of tables (by age group, screening history and screening policy): the upper series is for colposcopies performed following a positive Pap-test or a positive HPV test with positive triage test result (immediate referral); the lower series is for colposcopies performed following a positive early rescreen result (Early rescreen referral)

Table 10 Stage

Table 10. Stage distribution of cancers detected among women screened in the program

Immediate referral

		J1 Stage I	J2 Stage II	J3 Stage III	J4 Stage IV	Stage unknown	G4 to G7 Invasive cancers
Initial screening	Up to 19					0	0
	20-24					0	0
	25-29					0	0
	30-34					0	0
	35-39					0	0
	40-44					0	0
	45-49					0	0
	50-54					0	0
	55-59					0	0
	60-64					0	0
	65-69					0	0
	70-74					0	0
	75-79					0	0
	Unknown					4	4
	Total	0	0	0	0	4	4
Subsequent screening	Up to 19					0	0
	20-24					0	0
	25-29					0	0
	30-34					0	0
	35-39					0	0
	40-44					0	0
	45-49					0	0
	50-54					0	0
	55-59					0	0
	60-64					0	0
	65-69					0	0
	70-74					0	0
	75-79					0	0
	Unknown					0	0
	Total	0	0	0	0	0	0

Early rescreen referral

		J5 Stage I	J6 Stage II	J7 Stage III	J8 Stage IV	Stage unknown	G16 to G19 Invasive cancers
Initial screening	Up to 19					0	0
	20-24					0	0
	25-29					0	0
	30-34					0	0
	35-39					0	0
	40-44					0	0
	45-49					0	0
	50-54					0	0
	55-59					0	0
	60-64					0	0
	65-69					0	0
	70-74					0	0
	75-79					0	0
	Unknown					1	1
	Total	0	0	0	0	1	1
Subsequent screening	Up to 19					0	0
	20-24					0	0
	25-29					0	0
	30-34					0	0
	35-39					0	0
	40-44					0	0
	45-49					0	0
	50-54					0	0
	55-59					0	0
	60-64					0	0
	65-69					0	0
	70-74					0	0
	75-79					0	0
	Unknown					0	0
	Total	0	0	0	0	0	0

In this table, the total to be stratified (in the four columns from J3 to J5) is the total number (G4+G5+G6+G7) of invasive cervical cancers reported from table 7.

* The unknown cases are automatically calculated as the difference between the total (right column) and the sum of the four white columns.

There are two set of tables (by age group and screening history): the upper series is for colposcopies performed following a positive Pap-test or a positive HPV test with positive triage test result (immediate referral); the lower series is for colposcopies performed following a positive early rescreen result (Early rescreen referral)

UICC/AJCC/FIGO stage

Table 11. Interval cases

Table 11. Interval cancers

Index year: 2018 < May be different from 2018 (general data)

		Test sensitivity				Episode sensitivity		
		K1	K2	K3	K4	K5	K6	K7
		Cervical cancer detected within 12 months since last negative screening	Cervical cancer within the entire inter-screening interval	Negative screening test in 2018	SD cancers in 2018	Cervical cancer detected within 12 months since last negative screening	Cervical cancer within the entire inter-screening	Negative screening episode result in
Initial screening	Up to 19							
	20-24							
	25-29							
	30-34							
	35-39							
	40-44							
	45-49							
	50-54							
	55-59							
	60-64							
	65-69							
	70-74							
	75-79							
	Unknown							
	Total	0	0	0	0	0	0	0
Subsequent screening	Up to 19							
	20-24							
	25-29							
	30-34							
	35-39							
	40-44							
	45-49							
	50-54							
	55-59							
	60-64							
	65-69							
	70-74							
	75-79							
	Unknown							
	Total	0	0	0	0	0	0	0

Index year: Specify the index year the table refers to. This may differ from the index year specified in the “General data”.

Depending on the protocol adopted in your country/region, indicate for the calendar year corresponding to the reference year minus the screening interval

- **K7** the number of Screen Detected (SD) cancers in the reference year
- **K6** the number of individuals with a negative Pap-Test/HPV test in the reference year
- **K13** the number of individuals with a negative Pap-Test/HPV test and a negative colposcopy result

and then indicate in columns (K1-K3 / K6-K8) the number of interval cancers diagnosed during the first year following the last negative screening test and during the time period corresponding to the entire screening interval (by age group and screening history, if available).

The reported interval cancers can be counted after a negative screen (K6) or after a negative screen or a negative further assessment (K13). The sum of both negatives sets the denominators for the interval cancer rate.

Cervix			
	Indicator	**Numerator**	**Denominator**
2	**Invitation Coverage**	**B1**	**A1 : A2**
3	**Examination Coverage**	**B3**	**A1 : A2**
	Examination coverage (including opportunistic testing)	**B3+B4o**	**A1 : A2**
4	**Participation Rate**	**B2**	**B1**
	Participation rate on invited in [index year] for the 1st time	**C5**	**C1**
	Participation rate on invited in [index year] and already invited in previous rounds	**C6**	**C2**
	Participation rate on invited in [index year] and already invited in previous rounds who did not attend in the previous round	**C8**	**C4**
5	**Retention Rate** Participation rate on invited in [index year] and already invited in previous rounds who attended in the previous round	**C7**	**C3**
6	**Test Result**	**D***	**B4**
7	**Positive Predictive Value recall**	**G4-G12**	**E1**
	PPV CIN2+	G4-G8+G10-G11	E1
8	**False Positive Rate**	**G3**	**E1**
9	**Episode Sensitivity**	**Table 11**	
10	**Compliance with Triage**	**D2+D3**	**D2+D3+D4**
11	**Compliance with Early Rescreening**	**F1**	**D3**
12	**Compliance with Further Assessment**	**E1**	**D1+D2**
13	**Detection Rate**	**G***	**B4**[&]
	Detection rate CIN2+	G4-G8+G10-G11	B4[&]
	Detection rate invasive	G4-G8	B4[&]
14	**Compliance with Treatment referral**	**I3**	**I1**
16	**Complications Further Assessment**	**H***	**G***
17	**Opportunistic Testing**	**B4o**	**B4**
19	**Interval Cancer Rate**	**Table 11**	

Instead of B4, if B5 is documented, B5 is used as denominator for indicators on DR

Grazie per l'attenzione!

TEAM

WP 3

In charge of: **Designing data collection tools and developing a data warehouse and web application to be housed in ECIS server**

Dr. Carlo Senore
WP Leader

Dr. Livia Giordano
WP co-leader

Dr. Paola Armaroli
Senior expert

Dr. Gianluigi Ferrante
Junior expert

Mrs. Roberta Castagno
Administrative staff

Mr. Mariano Tomatis
IT expert - consultant

Dr. Cristiano Piccinelli
Junior expert

CanScreen-ECIS has received funding from the EU4Health program under Grant Agreement No 101056947