

## **HPV Prevention and Control Board Meeting on:**

**The role of HCP in HPV vaccination  
and screening programme implementation –  
Prevention and control of HPV and HPV related cancers in Romania  
BUCHAREST, ROMANIA, 15-16 /05/2018**

### **HPV Primary Screening in Romania**

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## □ Introduction – rationale (why HPV screening?)

**A. Cervical cancer incidence and mortality rates are the highest among EU (GLOBOCAN2012)**

**Main cause:**

Diagnosis of cervical cancer especially in advanced stages because of

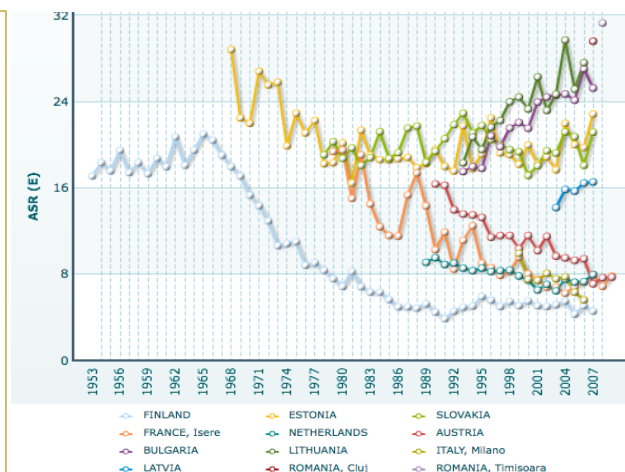
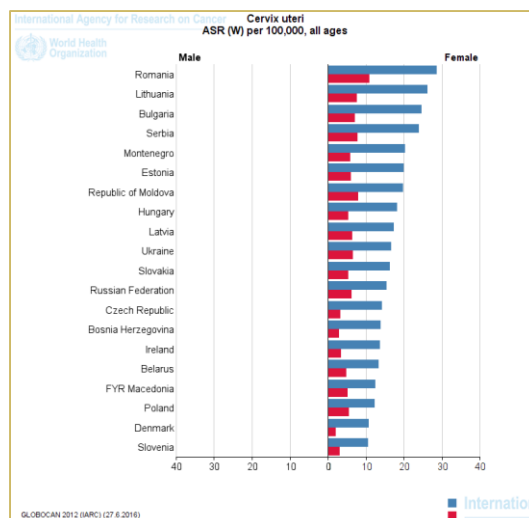
low QA/QC capacity of national organised cervical cancer

screening program: screening intensity

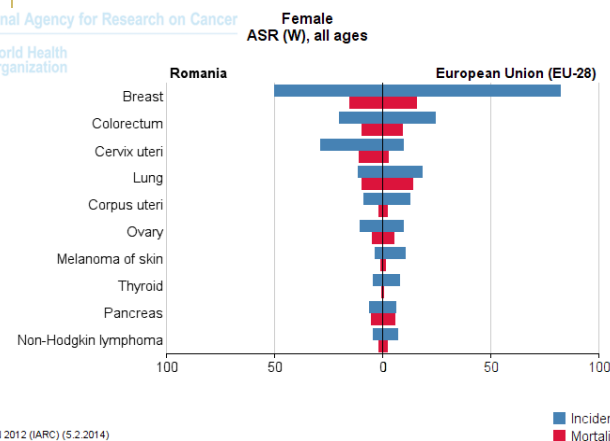
**test QA**

**follow-up QA**

Incidence and mortality by cervical cancer, Europe, 2012



International Agency for Research on Cancer  
World Health Organization



|                                 | IA<br>(N)<br>% | IB-IIA<br>(N)<br>% | >IIB<br>(N)<br>% | Nec.<br>(N)<br>% | Total<br>(N) |
|---------------------------------|----------------|--------------------|------------------|------------------|--------------|
| <b>Romania</b>                  | 71             | 148                | 642              | 357              |              |
| <b>NW Region (2006 – 2009)*</b> | 5,63           | 11,73              | 50,87 (!)        | 21,70            | 1262         |
| <b>Finland</b>                  | 332            | 552                | 482              | 180              |              |
| <b>(2000 – 2009)**</b>          | 21,47          | 35,71              | 31,18            | 11,64            | 1546         |

**IARC Reports on cancer screening programs implementation in EU Member States - 2007 / 2016**  
**-based on IOCN Screening Management Unit work:**  
**1996-2003 phaesability study and pilot organised cervical cancer screening planning-regional**  
**2002-2008 – cervical cancer screening organised regional pilot**  
**2012 – National roll -out**

Distribution of Cervical Screening Programmes based on Cervical Cytology in the EU in 2007

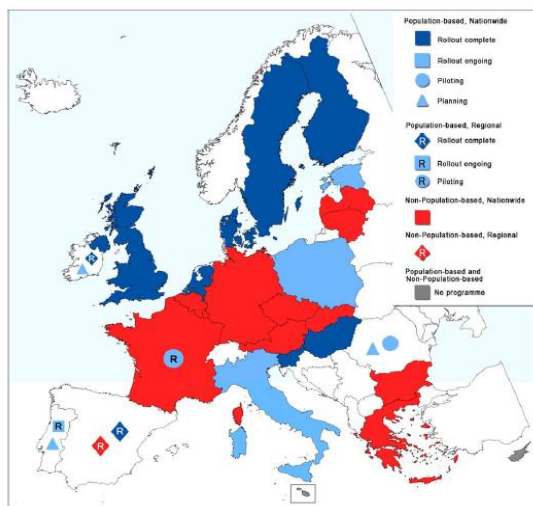
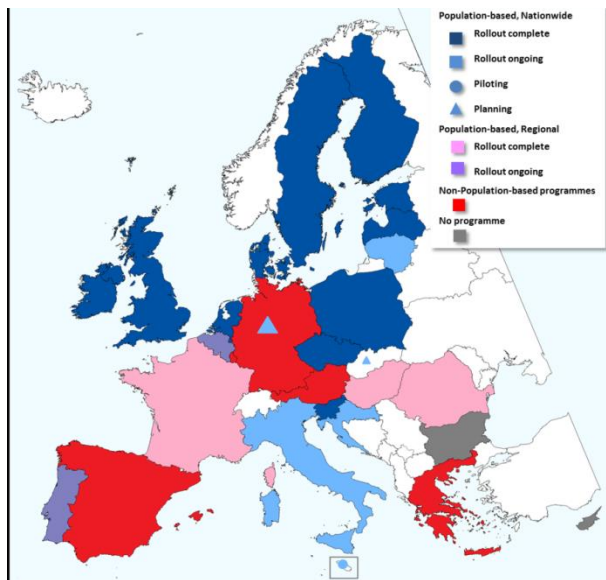
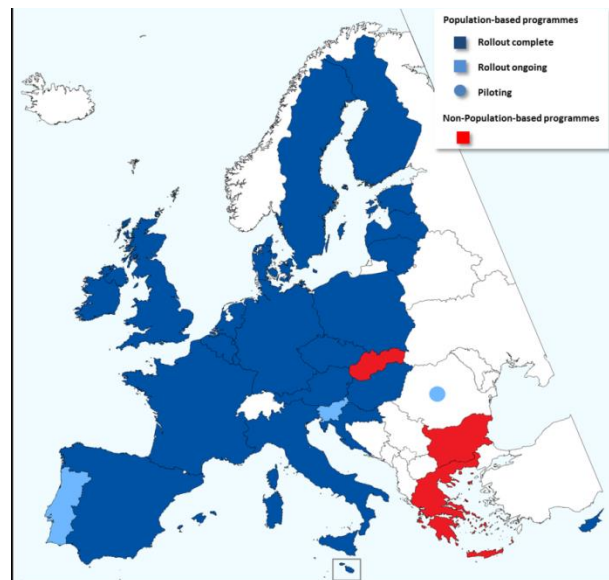


Figure 4 a. Cervical cancer screening programmes in the European Union in 2007, by programme type (population-based; non-population-based; no programme or unknown) and country implementation status (population-based: nationwide or regional, rollout complete or ongoing, piloting and/or planning; non-population-based: nationwide or regional, rollout complete or ongoing, piloting and/or planning; no programme).

Status of implementation of cervical cancer screening programs in EU Member States in 2016



Status of implementation of breast cancer screening programs in EU Member States in 2016



**2014-2017 HPV primary cervical cancer screening regional pilot – CEDICROM – Norway Funds**

**2018-2023 MoH planning of roll-out to 4 DR – EU Funds –promotor IOCN together with,NIPH**

# **CEDICROM Project – Why HPV Primary screening in Romania ?**

- ▣ proved better test performance
- ▣ low human and BP labs QA/QC
- ▣ Ahti Antilla' s “ empty table “ in organising cc screening in Romania– too late for start citotechnicians training in HPV era
- ▣ “ Door to door “ invitational sistem focused on defavorised groups in remote areas with mobile units, HPV added value to both assisted and self-sampling

**CEDICROM A – main objective :**  
**rising coverage of Organised National Cervical Cancer Screening Program**  
**( NCCSP ) and test QA/QC in compliance with European Guidelines ,**  
**integrating HPV primary screening according to EU Guidelines**

**Target population: 12.000 asymptomatic women between 25-64 years old**

Mainly suburban and isolated rural areas, targeting screening **uninformed and resistant** women  
paisans “moti, mocani “ in Apuseni Mountains, roma,slovakian, ukrainean, russian, hungarian, macedonian  
( one of two women at risk were tested in Cluj County tested in two 5 years screening rounds, mostly urban )

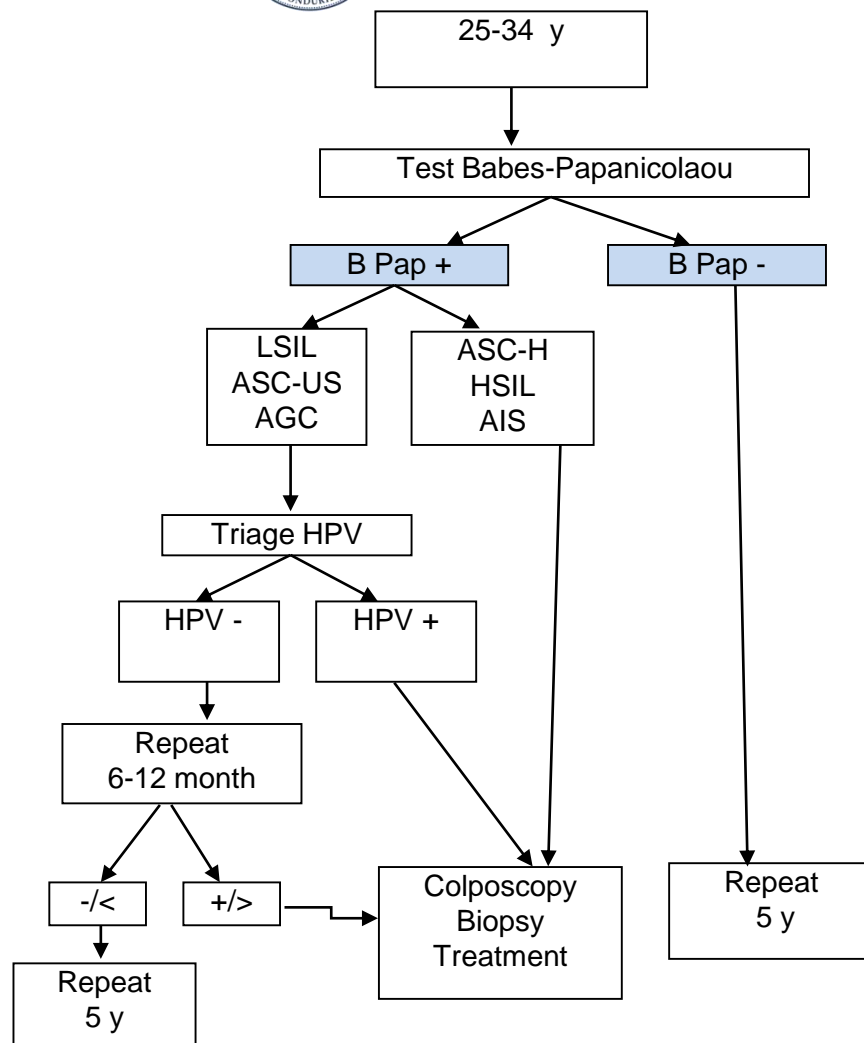
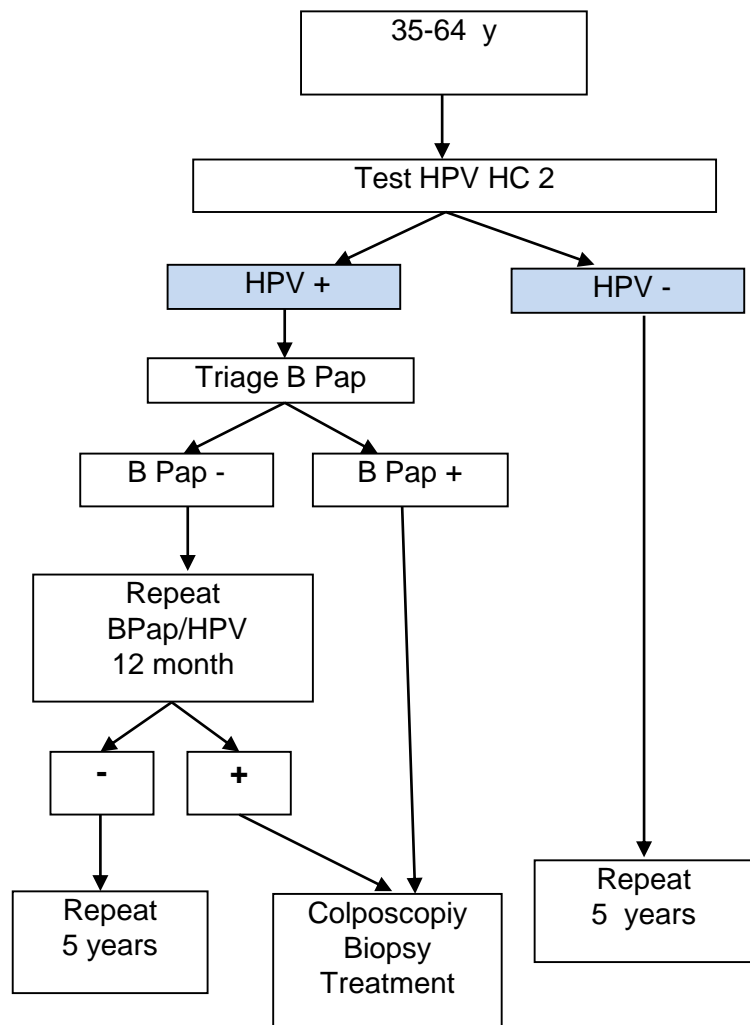
**Organisation of first public HPV screening dedicated lab**

**Organisation of HPV primary screening integrated in BP screening**

**HPV test information and informed consent with self-sampling possibility – Norway model**

**New screening strategy :**









## Information activities

- ▣ Partnerships with administrative leaders (Bihor, Bistrita Nasaud, Cluj, Salaj Counties ), schools, churches, ethnical groups, nongovernmental local organisations
- ▣ 78 informational activities in different communities, Romanian Cancer Society through sanitary mediators
- ▣ Activities:
  - 35.000 informative flyers distributed in communities
  - Meetings with groups of women at risk
  - - mass media – press conferences
- ▣ Counties visited: Cluj, Alba, Bacau, Bihor, Bistrita Nasaud, Constanta, Gorj, Hunedoara, Maramures, Satu Mare, Salaj, Tulcea, Vrancea, etc, mostly rural



**IOCN**  
Institutul Oncologic  
"Prof. Dr. Ion Chiriacu"  
Cluj-Napoca

**CANCER**  
Registry of Norway



**norway**



Campeni 31.07.2015





Proiect desfășurat de Institutul Oncologic "Prof. Dr. Ion Chiricuță", în calitate de Promotor, în parteneriat cu Oslo Universitetssykehus HF/Kreftregisteret din Norvegia, finanțat prin Granturile Norvegiene 2009-2014, în cadrul Programului RO 19 Inițiative în sănătatea publică, derulat de Ministerul Sănătății.

Project implemented by "Prof. Dr. Ion Chiricuță", as promoters, in partnership with Oslo UNIVERSITETSSYKEHUS HF/Kreftregisteret in Norway, financed by Norway Grants 2009-2014, within the Program RO 19 public health initiatives implemented by the Ministry of Health.



## SCREENINGUL CANCERULUI DE COL UTERIN



Creșterea capacității sectorului de sănătate românesc pentru a pune în aplicare programe de screening organizat pentru cancerul adecvat la intervenții de depistare precoce eficiente.

Increase capacity of the Romanian health sector to implement organized screening for cancers amenable to cost-effective early detection interventions.



[www.cedicrom.iocn.ro](http://www.cedicrom.iocn.ro)



**"Creșterea capacității sectorului de sănătate românesc de a pune în aplicare programe de screening organizat pentru cancer"**

**Proiect finanțat prin Mecanismul Financiar Norvegian 2009-2014 în cadrul Programului RO 19 Inițiative în Sănătate Publică**

În parteneriat cu

invităm femeile cu vârste cuprinse între 25-64 de ani să efectueze gratuit testul Babeș-Papanicolau (testul pentru depistarea precoce a cancerului de col uterin)

Recoltarea testului va avea loc în data de

la.....

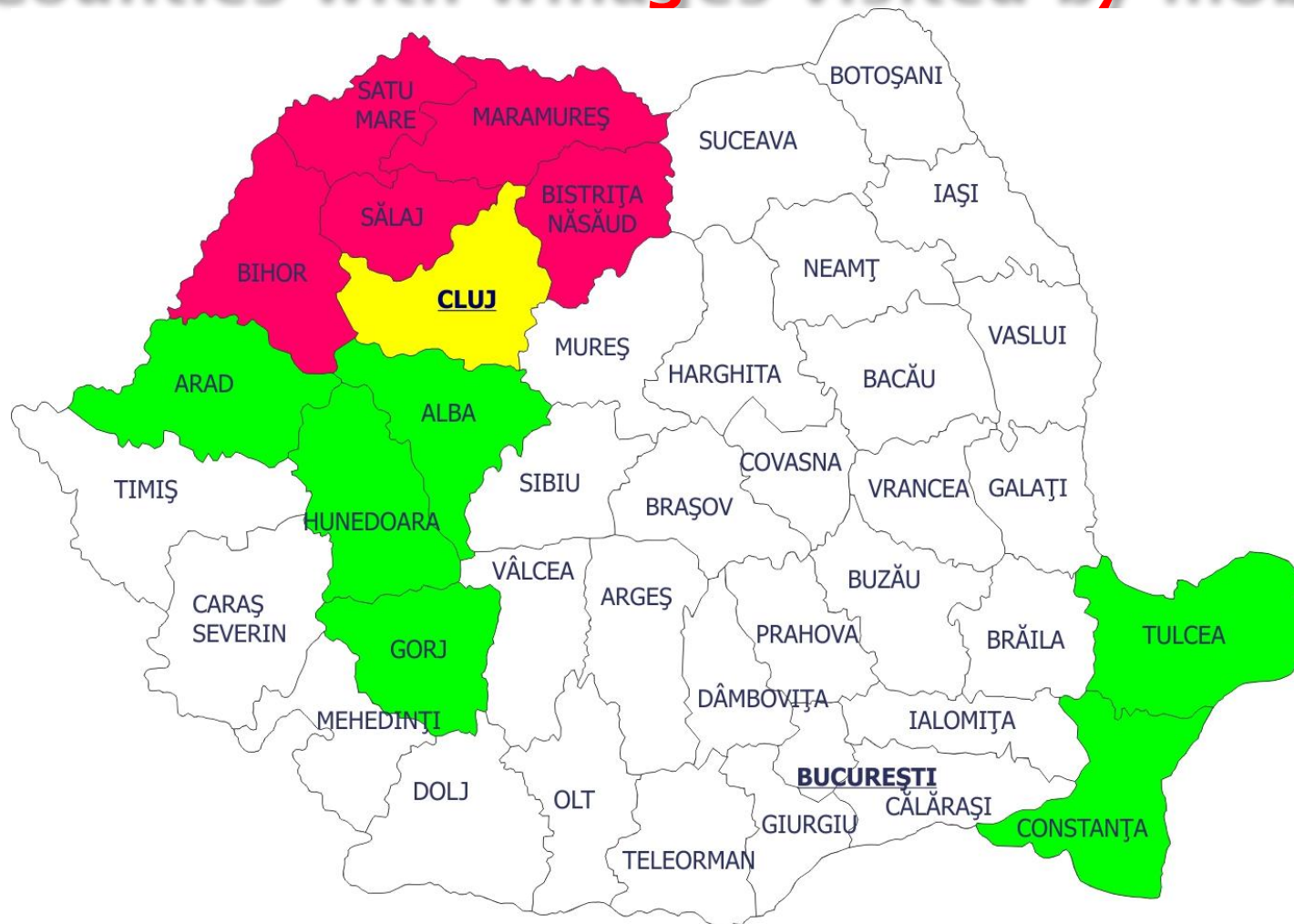
Programări pentru recoltare și informații

Testul se interpretează la Institutul Oncologic Cluj





# Counties with willages visited by mobile



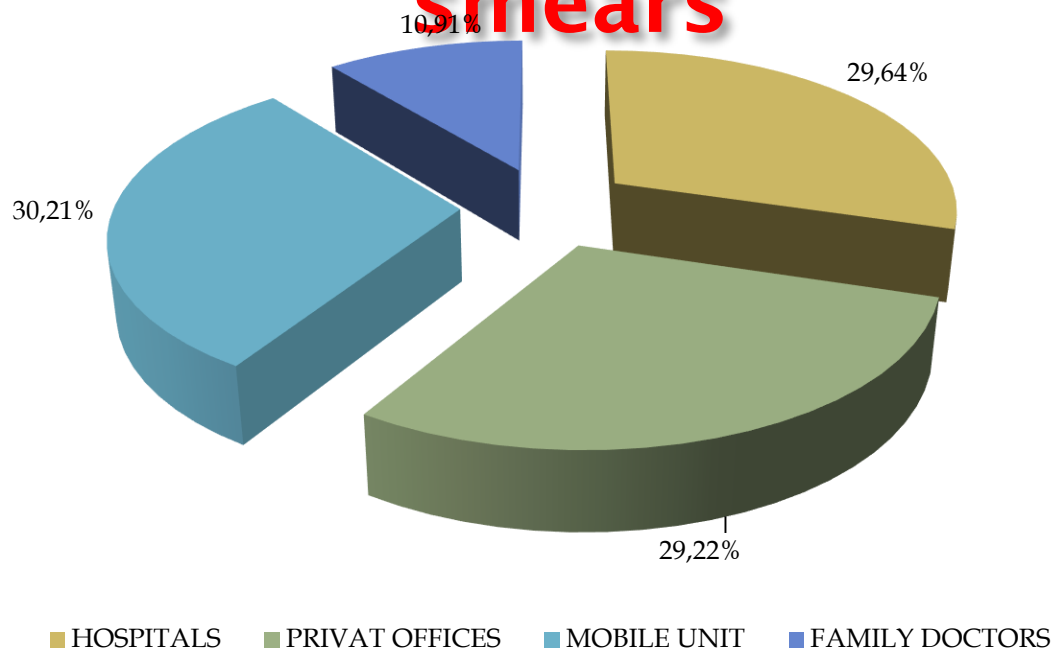




way  
nts



# CEDICROM network for taking smears



■ HOSPITALS ■ PRIVAT OFFICES ■ MOBILE UNIT ■ FAMILY DOCTORS

Number of  
tests

3032

2989

3090

1116

Source: CEDICROM Cytology Database



# CEDICROM screening voucher

**Formular screening pentru cancer de col uterin - Proiect CEDICROM**

**Secțiunea 1 (se completează la nivelul cabinetului de medicină de familie sau la nivelul centrului de recoltare)**

Serie formular **01151** CNP

Nume  Prenume

Adresa: județ  localitate  strada, nr.  tel.

Cabinet medical (nume, adresa, telefon)  medic de familie

☐ Urban ☐ Rural Etnia: ☐ romă ☐ ucraineană ☐ alte

Antecedente personale (bifați în căsuțele corespunzătoare)  
Histerectomie subtotală pentru: ☐ afecțiune benignă ☐ afecțiune malignă

**Secțiunea 2 (se completează la nivelul centrului de recoltare)**

Centru recoltare  Medic recoltor

Data recoltării  /  /  Data ultimei menstruații  /  /

Status hormonal ☐ Ciclică ☐ Sarcină ☐ Menopauză ☐ Lăuzie (12 săptăm.) ☐ Alăptare

Status postterapeutic pentru alt cancer decât cel cervical: ☐ postradioterapie ☐ postchimioterapie

Purtătoare de DIU ☐ Leucoree ☐ Sângerări: ☐ la contact ☐ spontane

Aspectul colului ☐ cu leziuni vizibile ☐ fără leziuni vizibile În antecedente: ☐ cauterizări ale colului ☐ biopsii de col (diagnostic/descriere )

**Secțiunea 3 (se completează la nivelul laboratorului de analize medicale)**

Citologie ☐ convențională ☐ în mediul lichid

Laborator

Personalul medical care efectuează citirea: medic de specialitate: anatomie-patologică   
(semnătura, parafă)

Medic laborator  biolog

Medic de specialitate anatomie-patologică care certifică rezultatele pozitive   
(semnătura, parafă)

Numărul lamei  Data primirii lamei  /  /  Data interpretării  /  /

Calitatea frotiului: ☐ satisfăcător ☐ nesatisfăcător pentru evaluare:

celule endocervicale/celule metaplazice: ☐ prezente ☐ absente

frotiu cu: ☐ exces de hematii ☐ exces de leucocite ☐ alte substanțe străine ☐ altele

Descrierea frotiului: ☐ Infecții

☐ Trichomonas ☐ Candida ☐ Gardnerella vaginalis ☐ Actinomyces ☐ Virusuri herpes simplex ☐ altele

☐ Anomalii ale celulelor epiteliale scuamoase

☐ ASC-US ☐ ASC-H ☐ LSIL ☐ LSIL cu atipii HPV ☐ HSIL ☐ HSIL cu suspiciune de invazie ☐ carcinom scuamos

☐ Anomalii ale celulelor epiteliale glandulare

☐ AGC endocervicale NOS ☐ AGC endometriale NOS ☐ AGC NOS ☐ AGC endocervicale în favoarea neoplaziei ☐ AGC glandulare în favoarea neoplaziei ☐ Adenocarcinom *in situ* ☐ Adenocarcinom ☐ endocervical ☐ endometrial ☐ NOS ☐ extrauterin

☐ Alte neoplazii

☐ Negativ pentru leziuni intraepiteliale sau maligne

Recomandări: ☐ repetare: ☐ deficiență de recoltare ☐ după tratament antiinfecțios / antiinflamator

☐ repetare de rutină dacă rezultatul este negativ

☐ conform protocolului în cazul rezultatului pozitiv

☐ biopsie ☐ chiuretaj endometrial ☐ testare HPV

☐ colposcopie ☐ chiuretaj endocervical

Observații

Data eliberării rezultatului  /  /

**Secțiunea 4 (se completează la nivelul Centrului de finalizare)**

☐ Colposcopie cod 35614-00; data  /  /

☐ Biopsie cod 35608-02; data  /  /

☐ Chiuretaj endocervical cod 35608-02; data  /  /

☐ Chiuretaj endometrial cod 35640-00; data  /  /

☐ Conizație cod 35618-00; data  /  /

☐ Histerectomie totală cod 35653-01; data  /  /

Distrucție: ☐ Cauterizare cod 35608-00 ☐ Diatermocoagulare cod 35646-00 ☐ Distrucție cu laser cod 35539-02

data  /  /

☐ Criocauterizare cod 35608-01

Semnătura, parafă ginecolog

Rezultat biopsie

Semnătura, parafă medic anatomopatolog

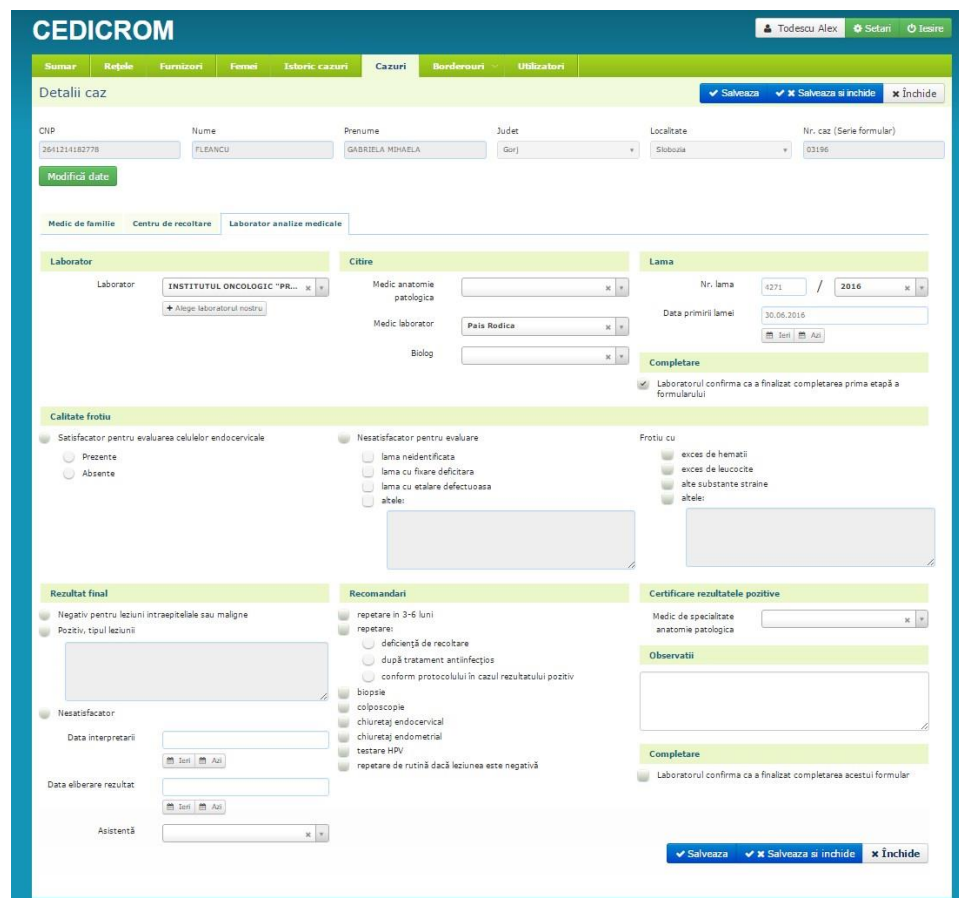
Rezultat HP piesa operatorie

Semnătura, parafă medic anatomopatolog

# CEDICROM screening database – online acces

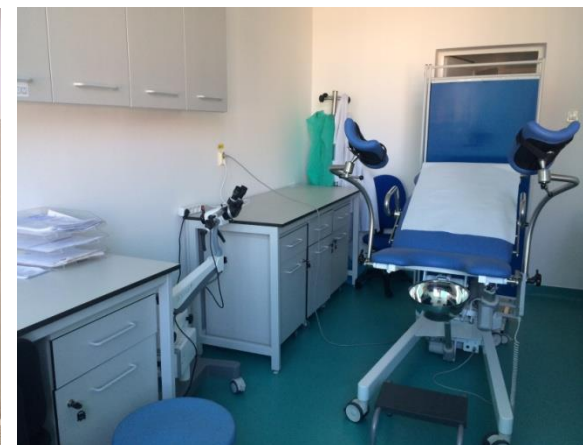
- web based application,  
on-line acces for all  
stakeholders

<http://oncologic.netlogiq.eu>



The screenshot displays the CEDICROM web application interface. At the top, there is a navigation bar with tabs: Sumar, Rețete, Furnizori, Femei, Istoric cazuri, Cazuri, Borderouuri, Utilizatori. The 'Cazuri' tab is selected. Below the navigation bar, there is a header section with the title 'CEDICROM' and user information 'Todescu Alex', 'Setari', and 'Iesire'. The main content area is titled 'Detalii caz' and contains a form for entering patient data. The form includes fields for CNP, Nume, Prenume, Judet, Localitate, and Nr. caz (Serie formular). Below these fields, there is a 'Modifică date' button. The form is divided into several sections: 'Medic de familie', 'Centru de recoltare', and 'Laborator analize medicale'. The 'Laborator' section includes a dropdown for 'Laborator' (currently showing 'INSTITUTUL ONCOLOGIC "PR..."') and a button 'Adăugați laboratorul nou'. The 'Către' section includes dropdowns for 'Medic anatomie patologică', 'Medic laborator', and 'Biolog'. The 'Lama' section includes a dropdown for 'Nr. lama' (currently showing '4271') and a date field for 'Data primirii lamei' (currently showing '30.06.2018'). The 'Completare' section includes a checkbox for 'Laboratorul confirmă ca a finalizat completarea prima etapă a formularului'. The 'Calitate frotiu' section includes radio buttons for 'Satisfactor pentru evaluarea celulelor endocervicale' (with sub-options 'Prezente' and 'Absente') and 'Nesatisfactor pentru evaluare' (with sub-options 'lama nedeterminată', 'lama cu fixare defectuasă', 'lama cu etalare defectuoasă', and 'alte:'). The 'Rezultat final' section includes radio buttons for 'Negativ pentru leziuni intraepiteliale sau maligne' and 'Pozitiv, tipul leziunii'. The 'Recomandari' section includes a dropdown for 'repetare în 3-6 luni' and a list of options: 'repetare', 'deficiență de recoltare', 'după tratament antiinfecțios', 'conform protocolului în cazul rezultatului pozitiv', 'biopsie', 'colposcopie', 'chiuretaj endocervical', 'chiuretaj endometrial', 'testare HPV', and 'repetare de rutină dacă leziunea este negativă'. The 'Certificare rezultatele pozitive' section includes a dropdown for 'Medic de specialitate anatomie patologică'. The 'Observatii' section includes a text area. The 'Completare' section includes a checkbox for 'Laboratorul confirmă ca a finalizat completarea acestui formular'. At the bottom of the form, there are buttons for 'Salveaza', 'Salveaza si inchide', and 'Inchide'.



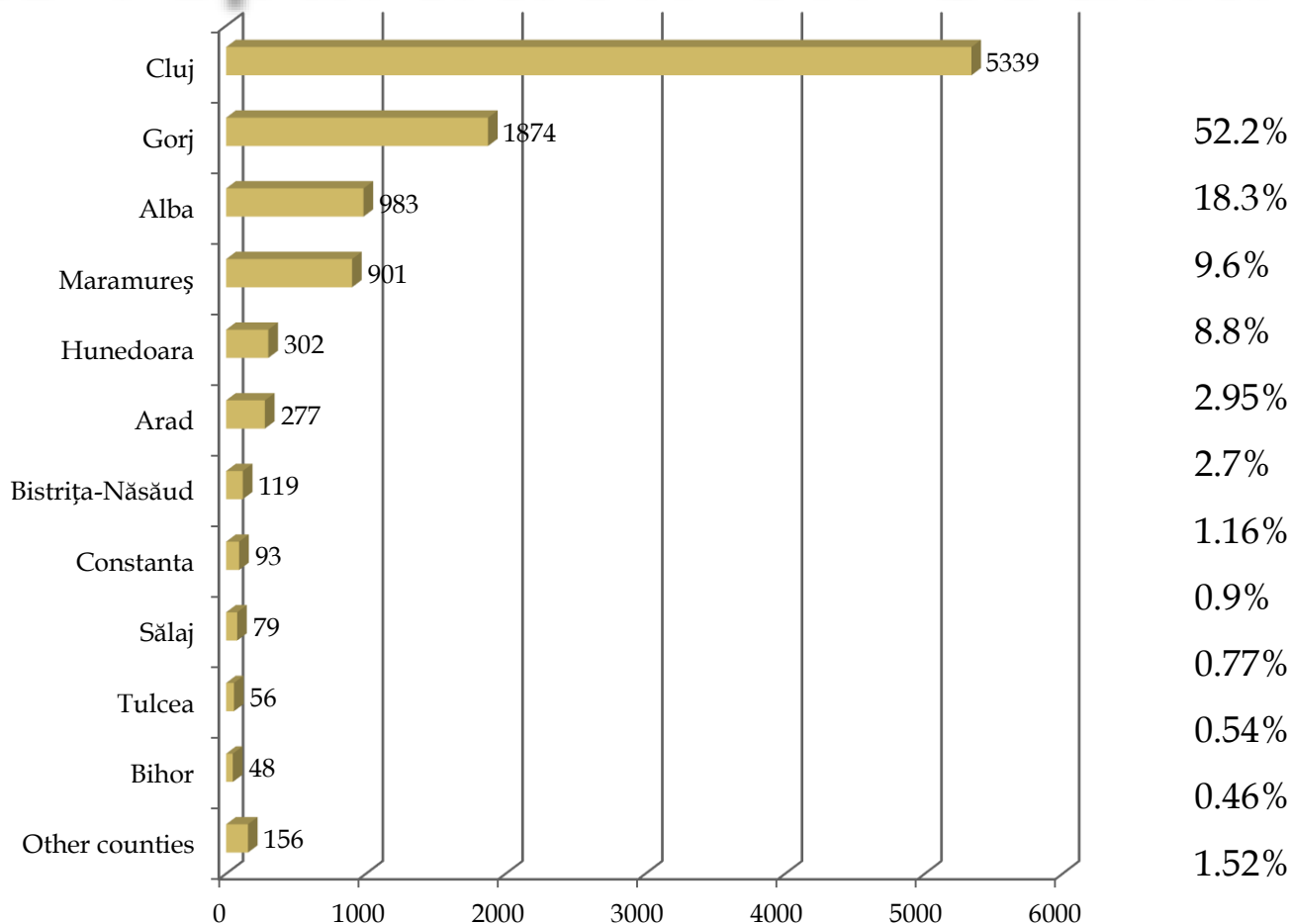


**High  
performance  
equipment for  
a reference  
screening  
center acquired  
within the  
project**



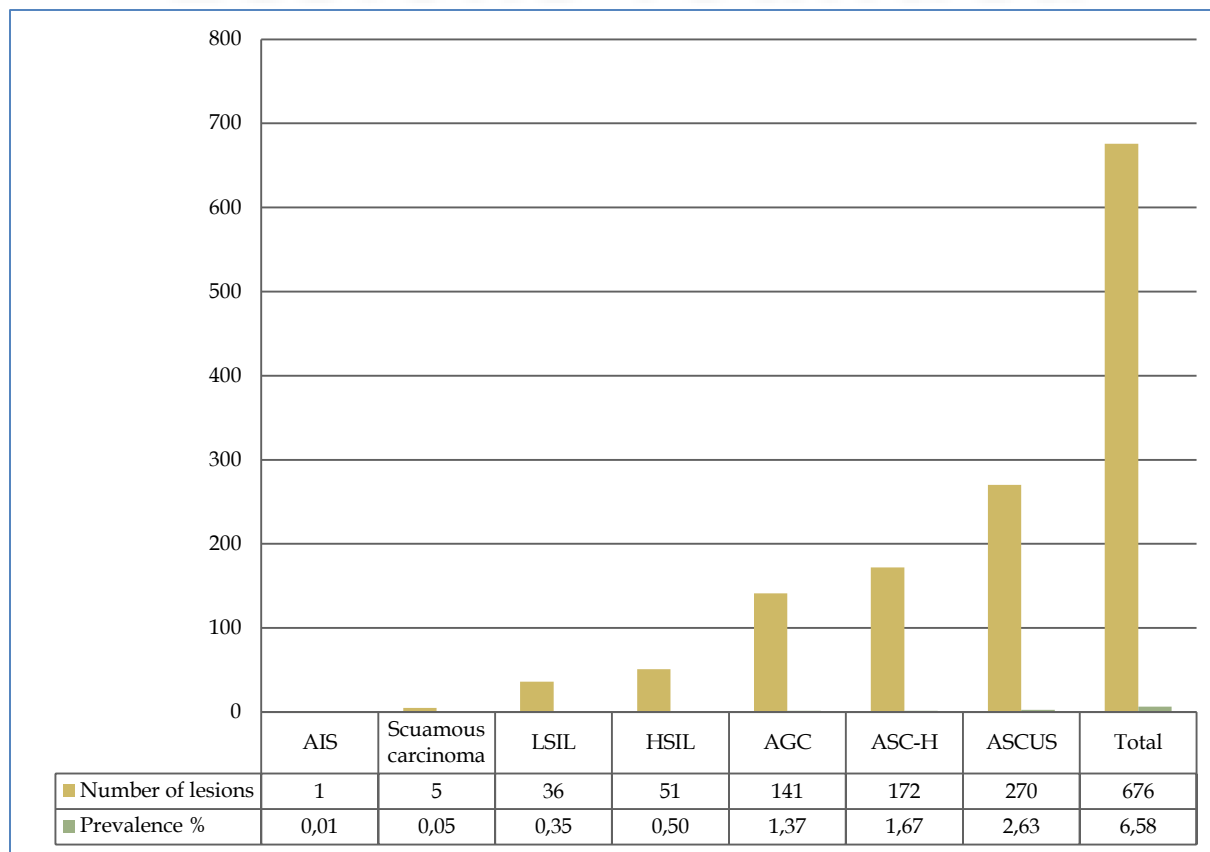


# Tets repartition on Counties



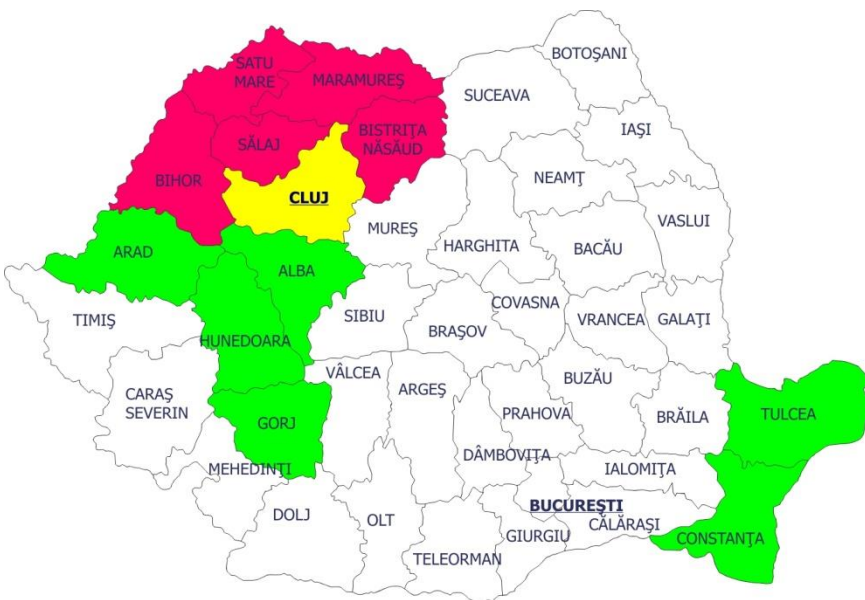
Source: CEDICROM Cytology Database

# Lesions founded

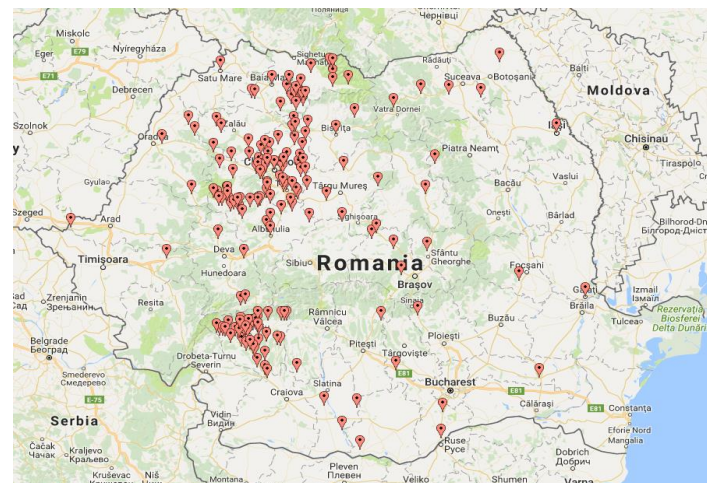




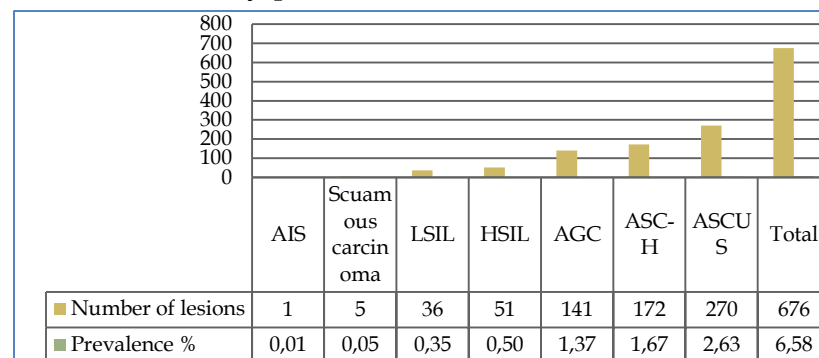
## 10.227 BP and 2.400 HPV tests– geographical distribution of positives



Cluj - 52%  
Gorj-18%  
Alba-9.6%  
Maramures-8.8%  
Hunedoara-3%  
Arad-2.7%  
Bistrita-Nasaud-1%  
Constanta-1%  
Salaj-0.8%  
Tulcea-0.5%  
Bihor-0.5%



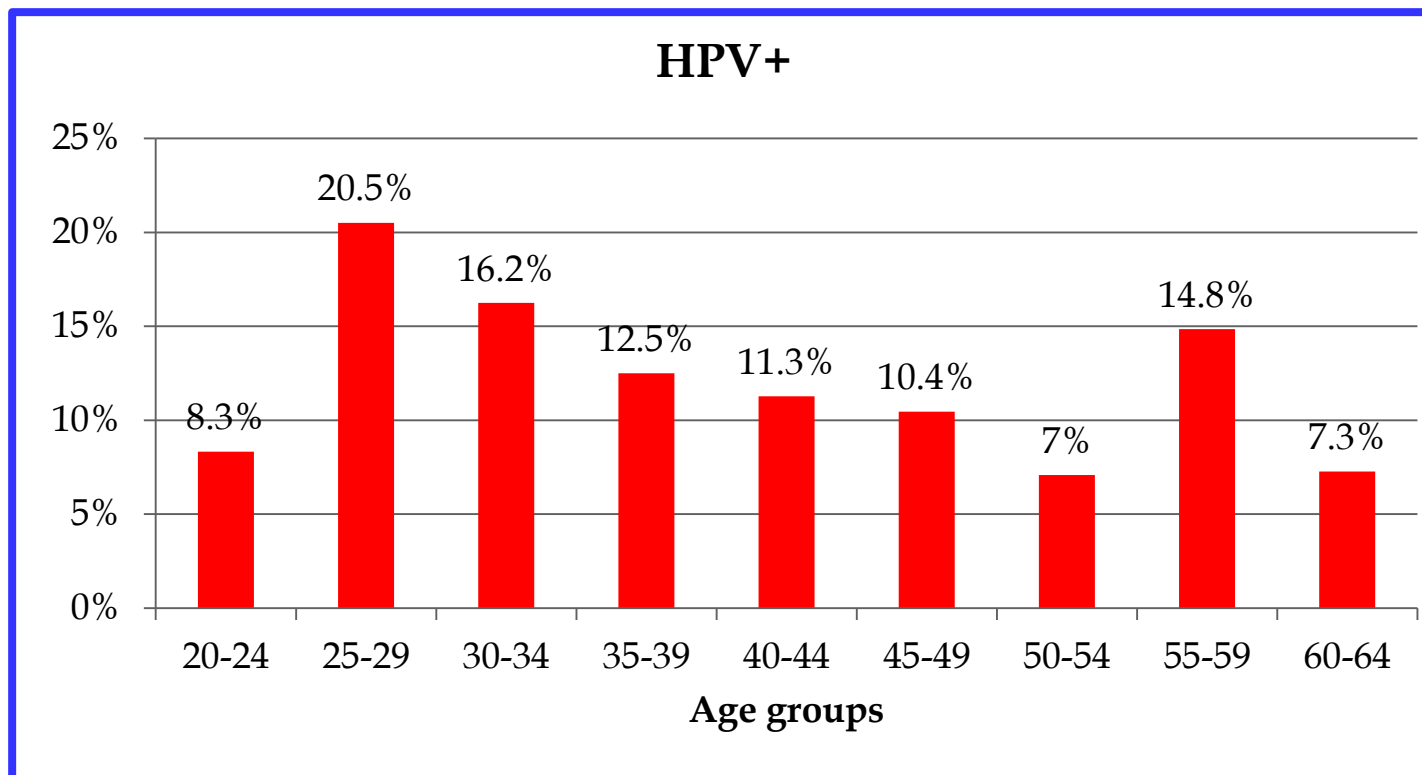
### Dysplasia and cancers detected



Source: CEDICROM Cytology Database

Unsatisfactory smears = 4,07% (419)

# HPV+ prevalence CEDICROM



## HPV+ prevalence related to dysplasia in different ethnical groups

| Cytology        | Etnie      |       |              |       |               |      |               |       | Prevalence (%) |
|-----------------|------------|-------|--------------|-------|---------------|------|---------------|-------|----------------|
|                 | Roma (%)   |       | Romanian (%) |       | Slovakian (%) |      | Ucrainian (%) |       |                |
| ASCUS           | 4          | 2%    | 43           | 5.6%  | -             | -    | 3             | 5%    | 50 (4.7%)      |
| ASC-H           | 4          | 2%    | 34           | 4.4%  | -             | -    | -             | -     | 38 (3.6%)      |
| LSIL            | -          | -     | 6            | 0.8%  | -             | -    | -             | -     | 6 (0.5%)       |
| HSIL            | 1          | 0.5%  | 6            | 0.8%  | -             | -    | 1             | 1.7%  | 8 (0.7%)       |
| AGUS            | 1          | 0.5%  | 19           | 2.4%  | -             | -    | -             | -     | 20 (1.9%)      |
| HPV+ total      | 10         | 5.1%  | 108          | 13.9% | 0             | -    | 4             | 6.8%  | 122 (11.6%)    |
| HPV -           | 155        | 79.5% | 666          | 86%   | 20            | 100% | 55            | 93.2% | 897 (85.5%)    |
| Unsatisfacatory | 30         | 15.4% | -            | -     | -             | -    | -             | -     | 30 (2.8%)      |
| Total           | 195 (100%) |       | 774 (100%)   |       | 20 (100%)     |      | 59 (100%)     |       | 1048*          |

# CEDICROM Main Results

- ▣ CEDICROM rised screening intensity = PARTICIPAtTION - information + direct acces to BP și HPV tests
- ▣ CEDICROM used 3 mobile units, performing 175 visits in rural and suburban communities, taking 3023 BP and 2400 HPV primary screening samples, last 500 within a randomised self-sampling trial with 21% participating women from 2388 informed/invitaded, 36% chosing self-sampling ( data in proceesing for publication ).
- ▣ At last, but not least, IOCN reference regional pathology/HPV laboratory, colposcopy assesment/ treatment/follow-up ambulatory resources were updated with training, guidelines and new machines, being able now to follow entirely EU QA recommendations for both test and follow-up performances.
- ▣ CEDICROM certainly rised awareness on cervical cancer prevention issues among such groups of women and in general population in isolated and underserved areas on cervical cancer prevention, and among care providers and decisionmakers.



# CEDICROM impact

- ▣ CEDICROM released evidences that already improved NCCSP methodology in terms of information/invitation/acces – MoH Order 377 from 03.03.2017, targeting rising screening intensity, introducing direct acces of women at risk to gynaecologic ambulatories and mobile units
- ▣ CEDICROM already convinced MoH decision makers to invest in mobile units infrastructure for to all regional screening networks ( August this year more 8 units )
- ▣ CEDICROM concluded HPV primary screening regional pilot in may 2017 and promoted future sustainability and roll-out to other regions

# Further IOCN Projects

- ❑ Together with NIPH EU Funds - POCU 4.9. roll-out of HPV primary screening integration
- ❑ Phase I : Methodology, Training , National Information Campaign – HPV information dissemination through population and professionals involved
- ❑ Phase 2 : Implementation in 4 Regions X 140.000 tests in each Region
- ❑ Norway Funds – project on follow-up in communities in remote areas - one see and treat visit: HPV Care/colposcopy/coldcoagulation – CEDICROM 2
- ❑ Norway Research Funds – research project on stratified risk of HPV + women





For further information please visit:

<http://www.iocn.ro/>

<http://cedicrom.iocn.ro/>

<http://eeagrants.org/>

<http://www.norwaygrants.ro/>

<http://www.ms.ro/>

<http://www.initiativeinsanatate.ms.ro/>