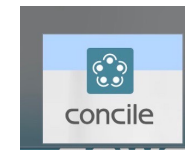


Digital Health Solutions for Cervical Cancer Screening

Our international partnership



Aims Cervical Cancer Prevention

General Aims

WHO global aims:
90% Screening; 90% vaccination;
70% access for treatment

Local Aims

Improvements of Infrastructures

- Deployment of sustained new technologies
- Patient - centered health care system
- Overcome urban – rural disparities



Measurement of Screening outcomes

General
Outcome
(WHO)

Decrease in Morbidity and Mortality

Eradication of Cervical Cancer (end of century)



Outcome
local



High participation rate of eligible population

(80% of 25 – 70 y)

Quality Management of screening test systems:

high sensitivity, specificity, PPV, NPV

(optimal > 90%)



Screening program in Malawi: Issues in outcome

Malawi Ministry of Health (MoH) 2016:

- National Cervical Cancer Control Strategy
- Digital registration program: “Digital Health Information System” (DHIS)
- One-day approach (VIA + treatment) primary health facilities + several referral units
- Eligible: women 25-49 y, every 3 - 5 y, yearly screening HIV positive women.
- National target: 80% screening coverage

Outcome (2016 – 2022):

- Increase from 11% to 34% screening coverage.

Screening barriers (main factors):

- A.) Understanding of CC disease; B.) information about the screening program, C.) limited access to screening unit

Results : VIA induced handling <1%, calculated CIN prevalence is 6 – 8% (> 30% CIN3)

Therefore: high false NPV (> 80%), still increase of advanced CC

How to solve these issues?

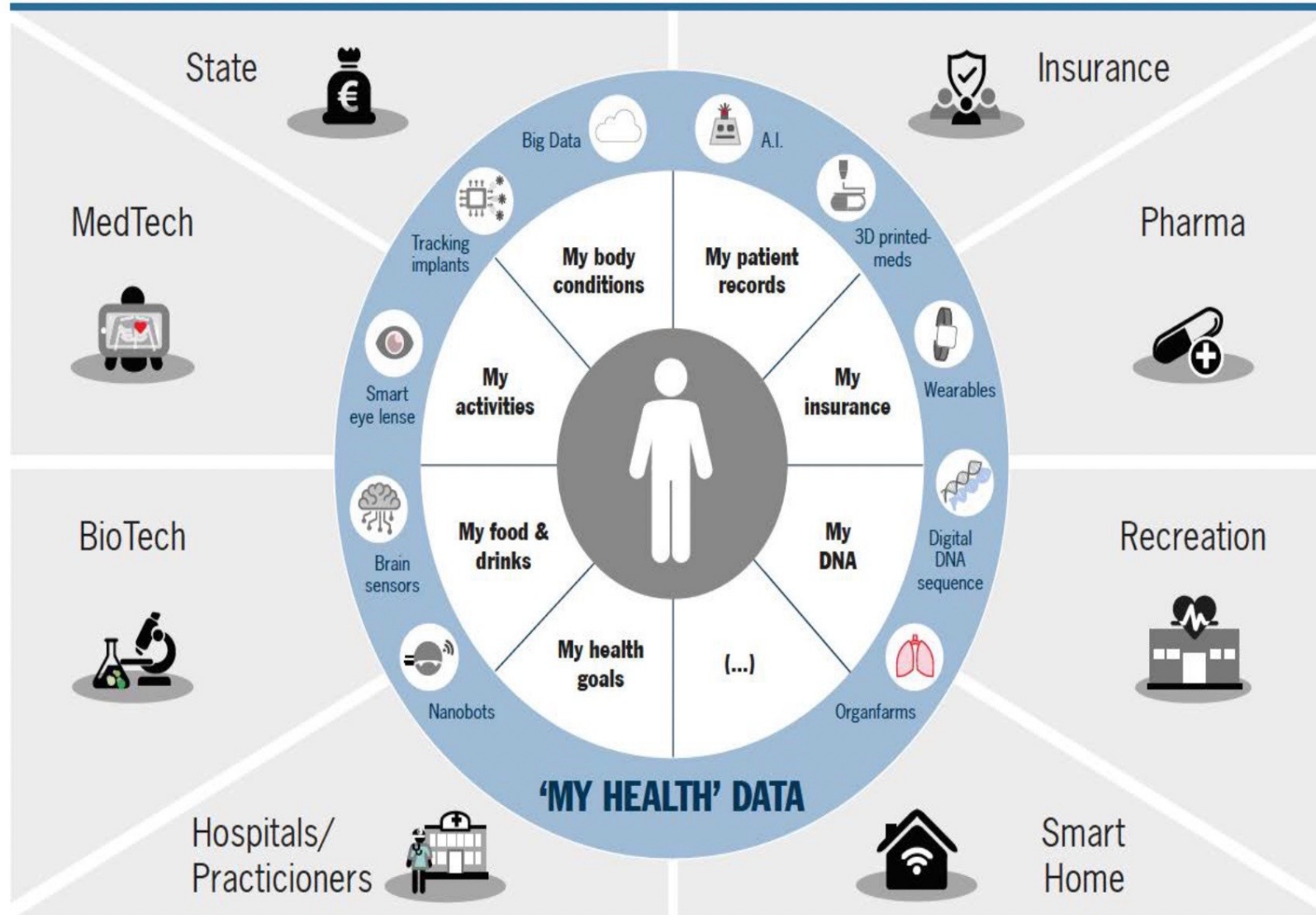
EDDA.one + hr-HPV-LFT + Colposcopy Screening Outcome Improvements

- Federated health data management (EDDA.One)
- Prescreening low vs high risk
Hr-HPV- based Lateral Flow Test (LFT) detects dysplasia
- Diagnose: Digital colposcopy (detection + histology)
- Treatment: Thermo-,Cryo- etc as 1-day approach

EDDA.One Technology

federated Data Management

PATIENT-CENTERED HEALTHCARE ECOSYSTEM



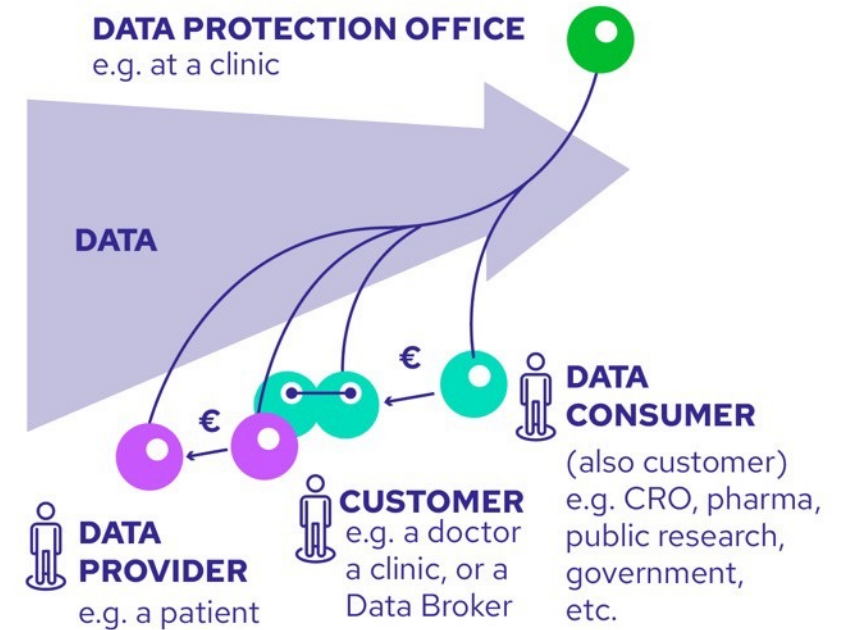
Federated Data management: EDDA.One

Subscription-based platform

- Data provider (Patient)
- Data consumer (Clinic, Government, etc)
- Data protection office (Clinic by patient consent)

EDDA.one leverages multiple functions:

- Communication
- Data replication on different devices
- No cloud service needed
- Patient profile management
- Accounting system (invoices; fees)
- Data transaction and trust (storage, privacy)
- Running all service systems: browser, PWA, API's and UI's, all mobile operating systems (MOS); Android, IOS; Linnux



EDDA.One

- Patient Dialogue and Education
- Support for Health Care Professionals
- Integration opensource platforms: e.g. DHIS



EDDA.One: User Interface; screenshots

Welcome to edda.one

edda.one is your Personal Health Record (PHR)

edda.one provides the necessary tools to manage your Electronic Health Record (EHR) without external dependencies. The app stores all your data directly on your device.

By visiting this website you already installed all necessary software, no further action is required. Below you can register with your own system and immediately start managing your health data.

It is important that you save your electronic keys somewhere safe. They allow you to recover your identity. The system will show you a copy button (Ⓞ) to get the keys. You can then enter them somewhere safe, e.g. in a chat.

You can make as many copies as you want to secure your data. Simply connect additional devices into one Internet of Me (IoM). edda.one will keep them up to date. You can also store regular snapshots on devices of people you trust.

LET'S GO

This is alpha software! Handling your own data is certainly risky, but having control of your data is most definitely bad.

- Home
- People
- Patients
- Questionnaires
- Self Assessment
- Journal
- Calendar
- Connections
- Settings
- IoM Requests
- Downloads
- About edda.one
- Debug-Tools

Thomas Bauknecht
bauknecht.1@gmail.com

GROUPS (3)

- Bin
- everyone
- glue.one

SOMEONES (1)

- Refinio LEUTE ONE Replicant
3_KJgd

CREATE CERTIFICATE

Object
Person (cb88594)

Issuer
TBD

Certificate Type
SignupCertificate

License Text
[signature.issuer] affirms that [person] has agreed to be signed up with edda.one by [signature.issuer] and store her data in the [person]'s name.

CREATE CERTIFICATE

CERTIFICATES (3)

- AffirmationCertificate**
Issuer: Thomas Bauknecht (cb88594)
Object: Person (cb88594) ✓
- RightToDeclareTrustedKeysForEverybodyCertificate**
Issuer: Thomas Bauknecht (cb88594)
Object: Person (cb88594) 👏
- RightToDeclareTrustedKeysForSelfCertificate**
Issuer: Thomas Bauknecht (cb88594)
Object: Person (cb88594) 👏

Cameroon Baptist Convention Health Services (CBCHS) Women's Health Program (WHP)

Instructions: Read this consent form to each woman who is to have DC while she is still dressed and seated on a chair, prior to performing her pelvic exam. Ask her if she has any questions and do your best to answer them. Explain cost of each procedure. If the self-collected HPV test is negative, she does not need to sign the consent or fill out the PE form (unless she has symptoms that need to be evaluated) and should be advised to have a repeat HPV test in five years or in 3 years if HPV positive.

[Consent and Physical Examination Form Rev Nov 2021](#)

The patient has read the declaration of consent and agrees to the conditions.

Consent Form for Digital Cervicography (DC), Cryotherapy, Thermal Ablation, and Biopsy


During this examination, you will be able to see your own cervix on the TV screen, and your Women's Health provider will explain what you are seeing and whether there is anything abnormal. The provider will also take up to three permanent photographs of your cervix: one before adding anything, one after adding vinegar, which turns precancers white, and one after a purple dye called Lugol's iodine that also helps show precancerous areas. We will use these photos for comparison when you come back for follow up or to send by e-mail to specialists for their opinion. We might also use them to train health care providers, for cervical cancer research, or to publish results of our work. If we use your photos for training, research, or publication, they will never be associated with your name and other identifying information, so that no one will know they are yours.

If your Women's Health provider finds that your cervix is abnormal during your exam, they will show you the problem on the TV screen and recommend one or more of the following tests or treatments, depending on the size and appearance of the abnormality. Ask your nurse or doctor any questions about the treatments they recommend. Even if you sign this consent form, you can still change your mind and refuse any treatment, if you do not want to receive it today, and you will not lose any health care benefits. The possible tests or treatments include:

- Cryotherapy (freezing) or Thermal Ablation (heating). These treatments are used to destroy early pre-cancers that are small enough to be covered with the probe (tip) of the machines. Both treatments are usually painless, although some women experience cramps. Neither requires anesthesia. After either of these treatments, you will probably have a watery vaginal discharge for about 3 weeks, as the dead skin falls off and new skin forms. You should avoid putting anything in your vagina (no douching, no sexual intercourse, no tampons) for 4 weeks. If you have sex sooner than 4 weeks, you should use condom to avoid catching any infections while your cervix heals. Having cryotherapy or thermal ablation at the same time as your exam will give you the best chance of successfully removing early pre-cancer, before it becomes too large for these treatments.
- Biopsy (cutting off a tiny [smaller than a bean piece of the cervix to send to a specialist [pathologist]to test for cancer or pre-cancer). We perform this procedure if an abnormal area looks like a more advanced pre-cancer, is suspicious for cancer, or is difficult to diagnose. Some women feel a mild pinch when a biopsy is taken, but no anesthesia is needed. You might have some light bleeding after a biopsy, but it should not last more than a few hours. You do not need to abstain from sexual intercourse after a biopsy. It takes about 1 month for the biopsy results to come back from the pathologist. Your Women's Health provider will phone you when the results are back, and may either tell you the results by phone or advise you to return to clinic to discuss results and treatment.

You can ask the WHP staff any questions that you have.

EDDA.One: screenshots cont



Name
Tom B

Birthday
2002-04-17

ADD

📄

📄




📷

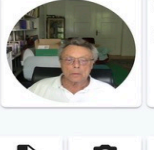
🌡️

💧

📖

DATA

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	Status (Image) Type: PersonImage Author: Thomas Bauknecht (cb88594) Owner: undefined (0000000)	2024.04.17 12:33
	Onboarding Type: QuestionnaireResponses_2_0_0 Author: Thomas Bauknecht (cb88594) Owner: Tom B (08939b8)	2024.04.17 12:46



Name
Tom B

Birthday
2002-04-17

ADD

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DATA

	Status (Text) Type: PersonStatus Author: Thomas Bauknecht (cb88594) Owner: undefined (0000000)	2024.04.17 12:31
	Status (Image) Type: PersonImage Author: Thomas Bauknecht (cb88594) Owner: undefined (0000000)	2024.04.17 12:33
	Onboarding Type: QuestionnaireResponses_2_0_0 Author: Thomas Bauknecht (cb88594) Owner: Tom B (08939b8)	2024.04.17 12:46
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	Body Temperature Type: BodyTemperature Author: Thomas Bauknecht (cb88594) Owner: Tom B (08939b8)	2024.04.17 13:00
	WBC Type: WbcObservation Author: Thomas Bauknecht (cb88594) Owner: Tom B (08939b8)	2024.04.17 13:01
	Diary Entry Type: DiaryEntry Author: Thomas Bauknecht (cb88594) Owner: Tom B (08939b8)	2024.04.17 13:02

INVITATIONS

Invitation link

🔗 [🔗 https://url%22%3A%22wss%3A%2F%2Fcomm10.dev.refinio.one%22%7D](https://url%22%3A%22wss%3A%2F%2Fcomm10.dev.refinio.one%22%7D)

CONNECT

QR-SCANNER

INTERNET OF ME

Devices ↑

Status ↑

Rows per page: 10 0-0 of 0 < >

ADD DEVICE

INTERNET OF PEOPLE

Person ↑

Status ↑

IoM ↑

Refinio LEUTE.ONE Replicant (5fe8c62)	<div style="width: 15px; height: 15px; background-color: red; border-radius: 50%; display: inline-block;"></div>	<div style="width: 15px; height: 15px; border: 1px solid blue; border-radius: 50%; display: inline-block;"></div>
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Rows per page: 10 1-1 of 1 < >

ADD PERSON

Validity: 14:49 ↻





Concile Cancer Check

HPV high risk Serum-based Lateral Flow Test

Prescreening Tool

Serum-based Lateral Flow test
of hr-HPV L1 antibodies produced
by HPV integrated dysplastic cells

Detection of CIN I - III

Sensitivity and Specificity > 90%

PPV 91,7% NPV 96,5%



Concile Cancer Check Working Station



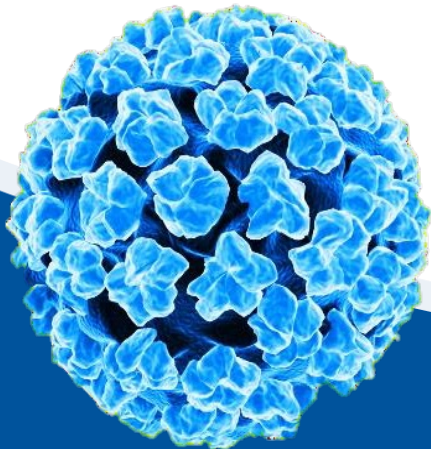
<https://www.sciencedirect.com/journal/clinical-epidemiology-and-global-health>

K. Bräutigam et al:

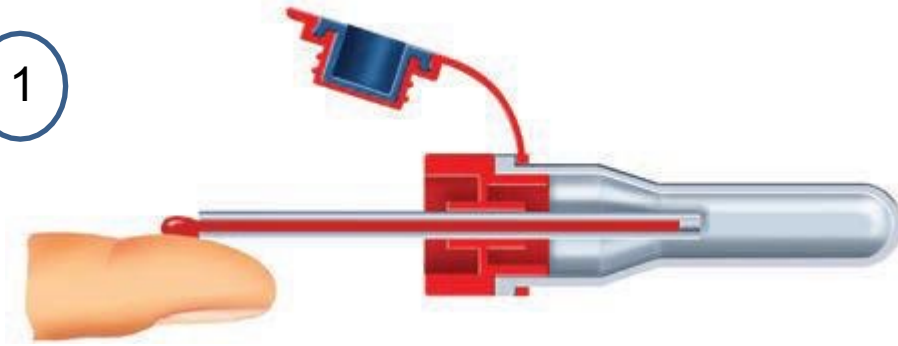
CER818: a highly specific and sensitive human papillomavirus (HPV) L1 high risk serological lateral flow rapid test for early detection of cervical cancer and its precursor lesions

PICTORAL TRAINING

CancerCheck HPV High risk



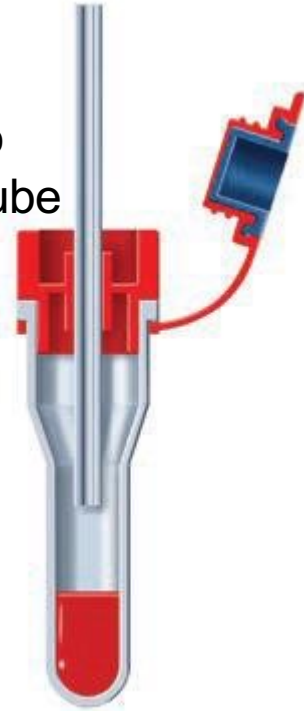
1



Take a troplet of blood from the finger tip using the capillary in the lid of the tube

2

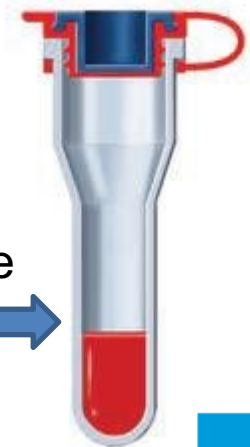
By turning it 90°, the blood sinks to the bottom of the tube

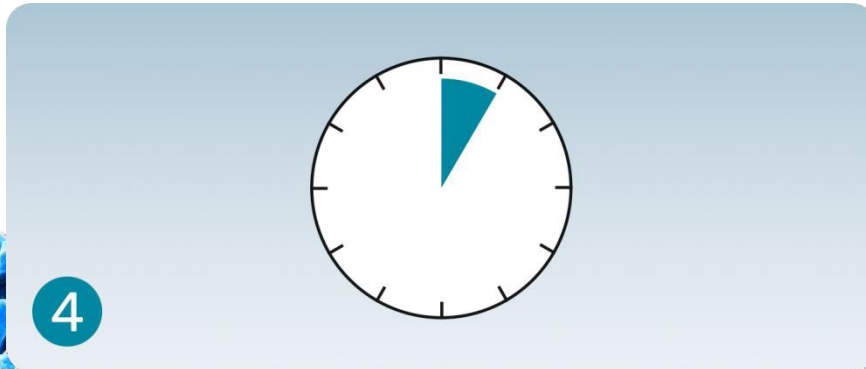
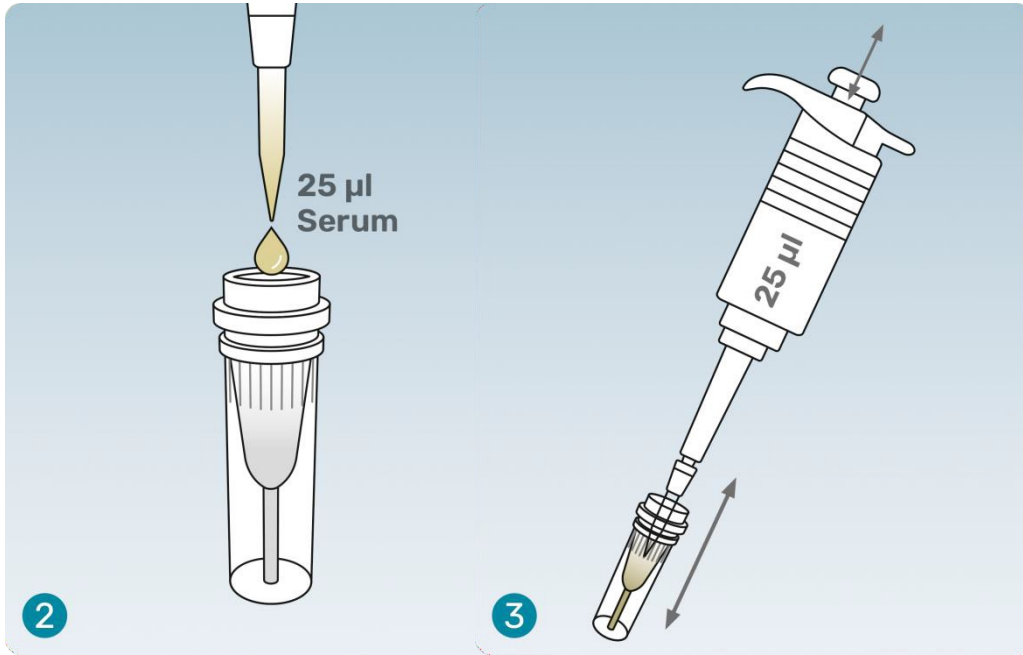


3

Remove the capillary, close the lid, and spin the vial for 10 seconds.

the serum sample is located above the gel



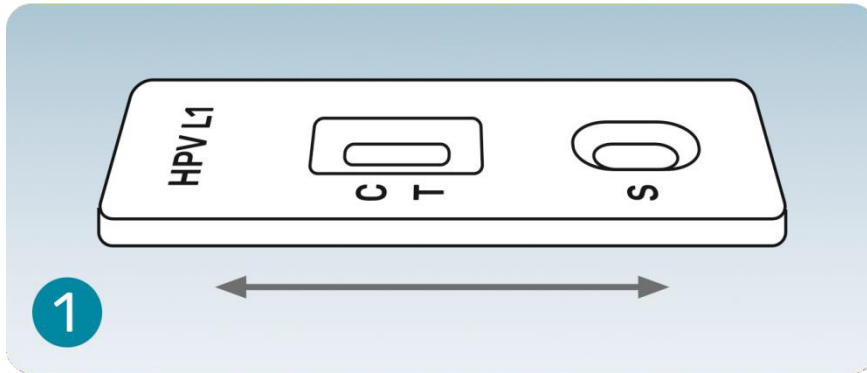


Incubate sample in HPV reagent
for 5 minutes.

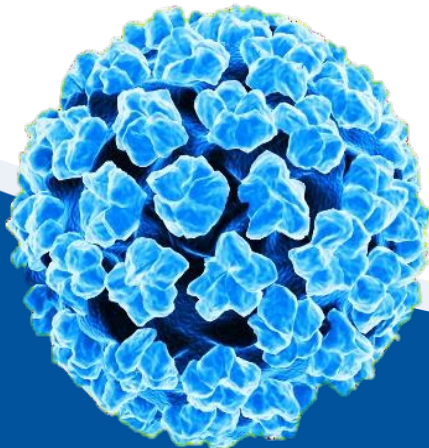


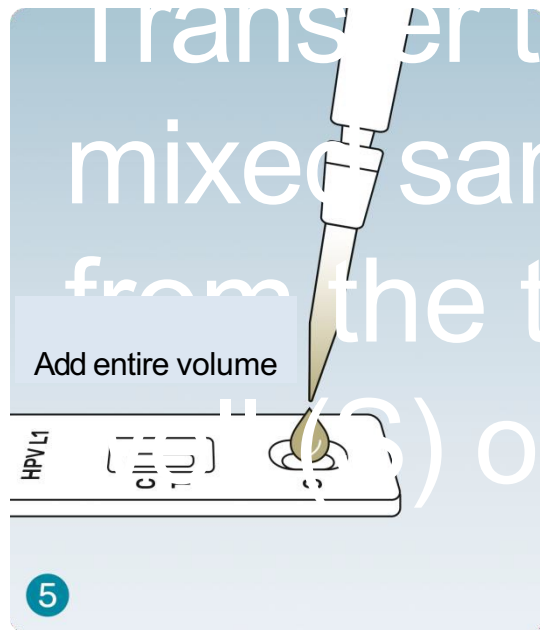
AB
AB CERRION

and down three

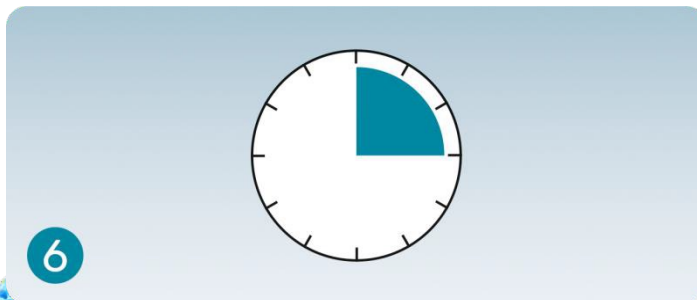


Immediately before performing the test, open the foil pouch, take out the test cassette and lay it on an even surface.



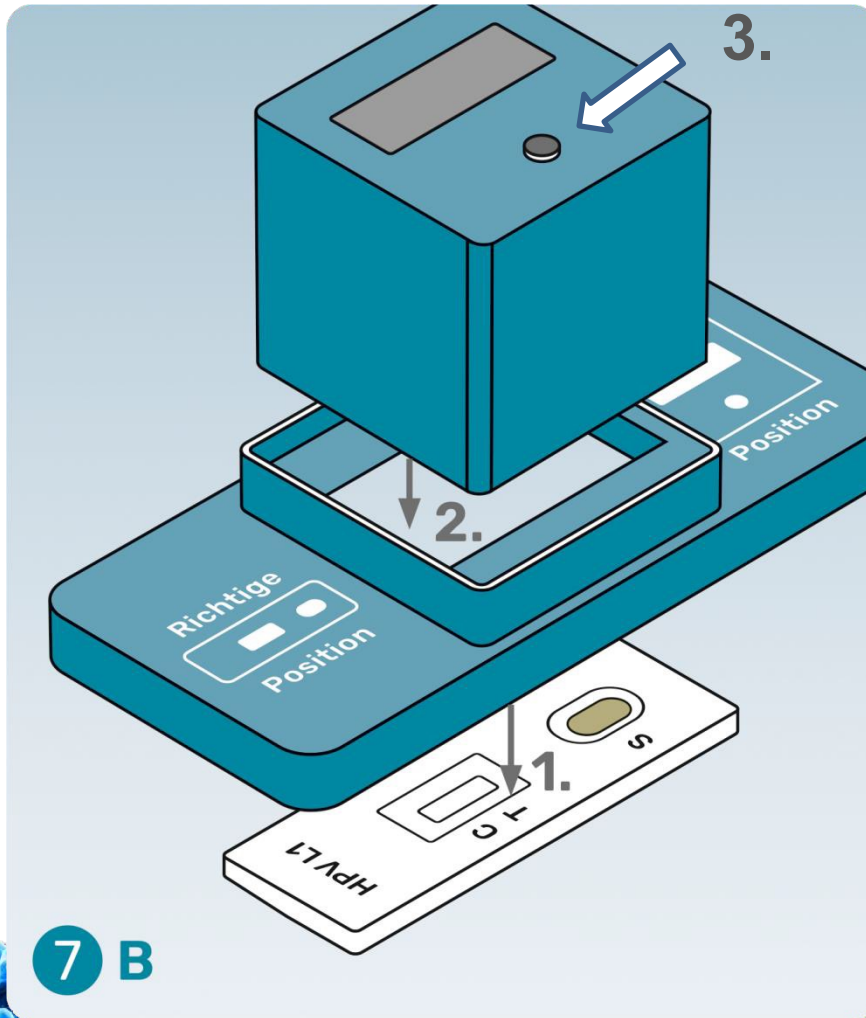


Avoid air bubbles in the sample opening (S) and do not allow any liquid to get into the reaction field



Measure the result 15 minutes after addition of the sample, then dispose of the test appropriately





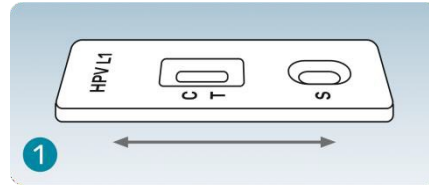
Put the adaptor onto the test cassette (1) and place the reader onto the adaptor (2).

Press the black button (3) on the top of the reader and follow the instruction in displayed in the display.

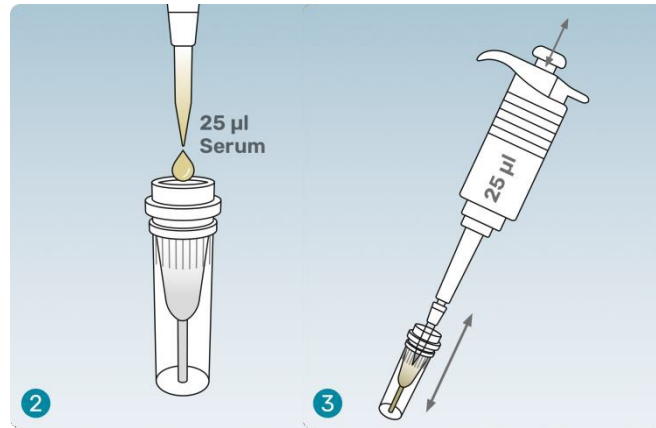
The test result is displayed as a numerical value in ng/ml accompanied by an acoustic signal.

7 B

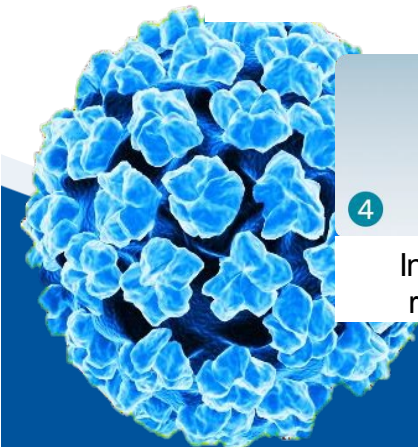




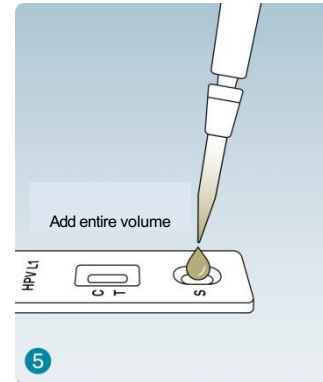
1 Immediately before performing the test, open the foil pouch, take out the test cassette and lay it on an even surface.



2 Add 25 µl patient serum to a tube with HPV reagent (100 µl) and mix the sample with the HPV reagent by pipetting up and down three times.

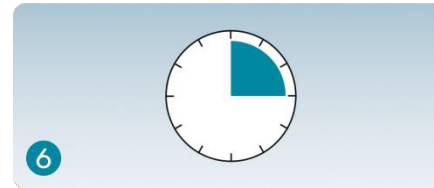


4 Incubate sample in HPV reagent for 5 minutes.

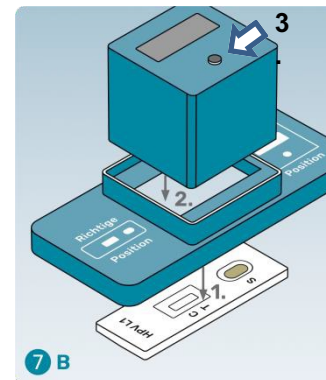


Transfer the entire volume of mixed sample and HPV reagent from the tube into the sample well (S) of the cassette.

Avoid air bubbles in the sample opening (S) and do not allow any liquid to get into the reaction field



6 Incubate sample 15 minutes.



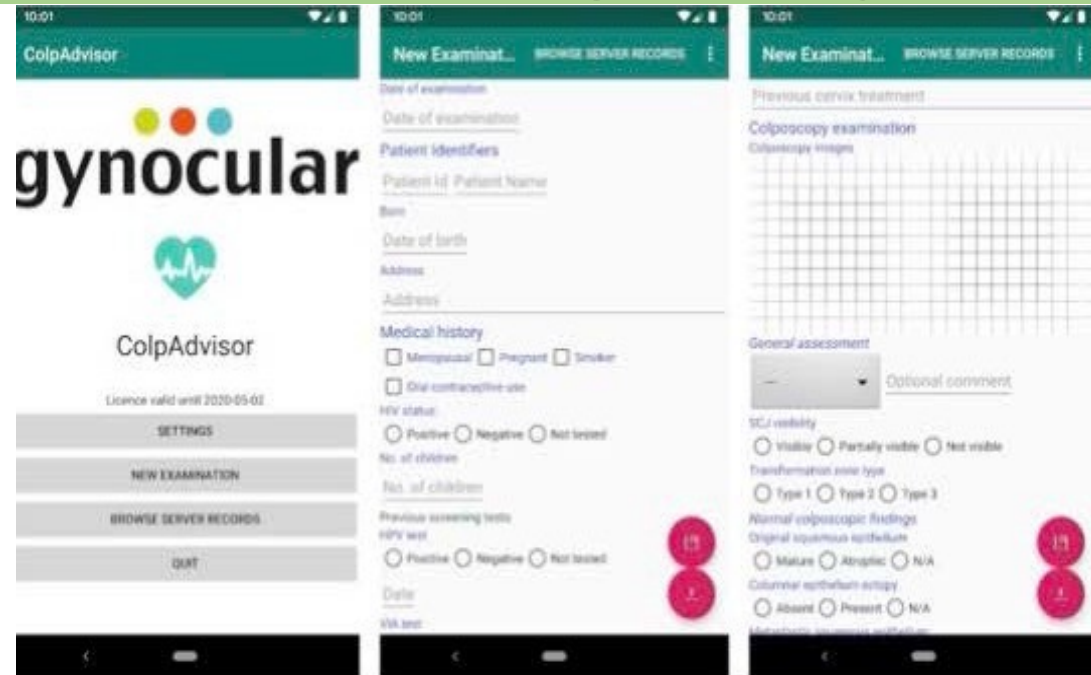
Put the adaptor onto the test cassette (1) and place the reader onto the adaptor (2).

Press the black button (3) on the top of the reader and follow the instruction displayed in the display.

The test result is displayed as a numerical value in ng/ml accompanied by an acoustic signal.

Gynius mobile Colposcope

Gynocular software AI support Image analysis

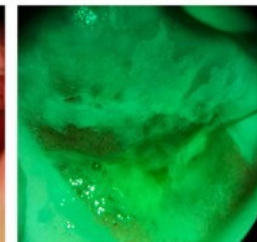


gynius
Age 33, HPV pos 16, Cytology scus, Biopsy CIN 3, LEEP CIN 2

Acetic Acid



Acetic acid green light



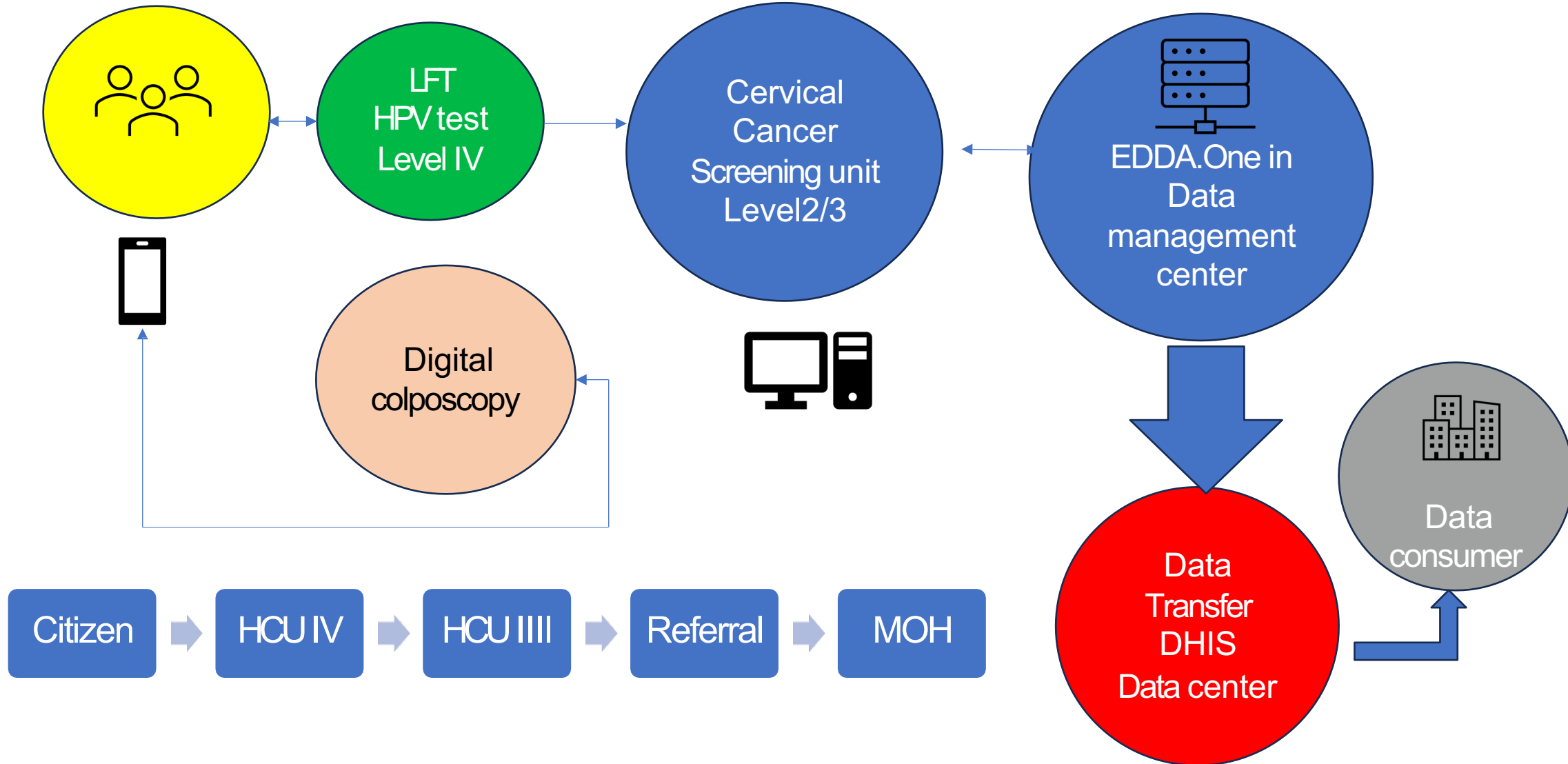
Luguls iodide



Regional Health Data Flow in CC screening

EDDA.one offered

- All key player inclusive patients as health data owner
- Highest Level of Trust and safety by patients consent



Preliminary results of ongoing Malawi pilot project

Lilongwe (capital of Malawi) – Malawi – study protocol

- 1.) Visit and presentation of the Project for MOH and the DHIS IT team
- 2.) Commitment to perform a pilot project in Karonga area (North Malawi)
- 3.) **Study endpoints:** Feasibility in rural based public HCU and private HCU;
enrollment number/site: 50 eligible women;
percentage of detected CIN lesion.
Business case calculation in case of public health service

Outcome so far:

- 2 sites started with enrollment of eligible women
- Site 1 enrolled 10 pts; site 2 enrolled 4 pts
- Onboarding + screening questionnaire in EDDA. One
- LFT testing in 10 pts, 6 pts LFT +,
- Colposcopy + biopsy in all CIN lesions; histology: 3 CIN 3 lesion

Cooperating Teams

Digitalization of CC Screening

SES* (Senior Expert Service) Delegate: Thomas Bauknecht
Visit Karonga (district Hospital + private HCU)
Topic: Support CC screening and Treatment
Applicant: Impact Malawi

QoL –Ma UG: <http://golma.net/>
Refinio GmbH: <https://refinio.net/>
Concile GmbH: <https://concile.de/>
Abcerion <https://abcerion-diagnostics.de/>
Gynius <https://gynius.se/>
Impact Malawi

CEO: Thomas Bauknecht
CEO: Jürgen Geck
CEO: Michael Maier
CEO: Ralf Hilfrich
CEO: Huaqing Li
CEO: Lameck Mphande



Next steps.....

- A.) Creation of a Morocco - EDDA.One - IT working group
Integration EDDA.One in the “National Digital Documentation System”
- B.) Training of HPV LFT testing + (digital) colposcopy
- C.) Transfer all medical data to EDDA.One Eco System
- D.) Initiate a cross sectional study by the use of HPV high risk LFT as a complementary procedure to primary HPV DNA screening approach