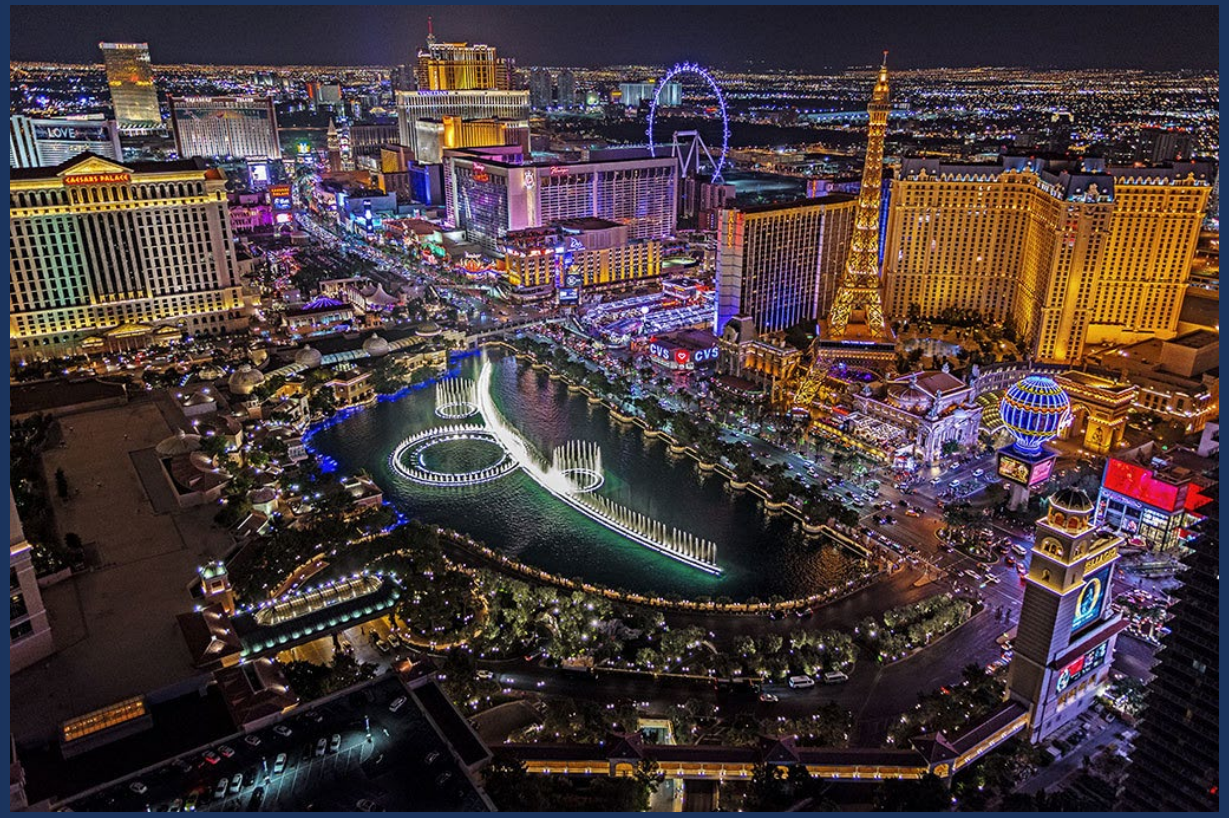
Standardized Structured Reporting and Future Perspectives
(*in pathology*)



Paul Seegers

Sr. Advisor & Administrator, National Pathology - & Molecular Protocols

Palga Foundation, Netherlands

Future of Cancer Data: Harnessing the Potential of Pathology Data, October 18th,2024, Las Vegas

palga Impact door inzicht

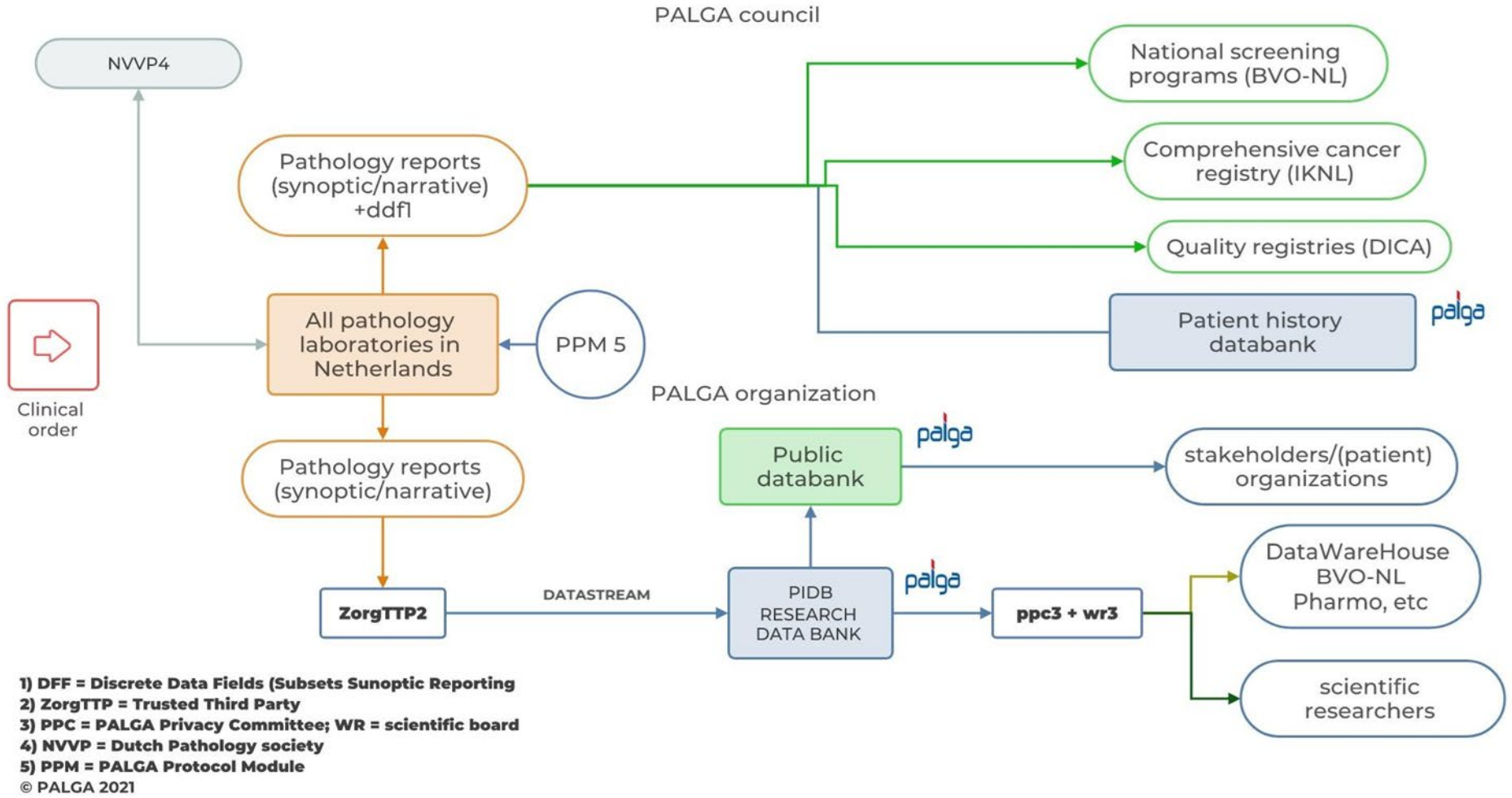
I have no conflict of interest to disclose

Outline

- A short introduction to Palga
- Standardized Structured Reporting (SSR) & benefits
- The layers of interoperability
- Timeline implementation & development of SSR (Palga)
- Future perspectives
  - Artificial intelligence
  - MOT/MTB with molecular diagnostics & patient outcome
  - Personal Health Environment (PHE)
  - *European Health Data Space (EHDS)*
- Take home messages

A short introduction to Palga

National Pathology Databank



1) DFF = Discrete Data Fields (Subsets Sunoptic Reporting
2) ZorgTTP = Trusted Third Party
3) PPC = PALGA Privacy Committee; WR = scientific board
4) NVVP = Dutch Pathology society
5) PPM = PALGA Protocol Module

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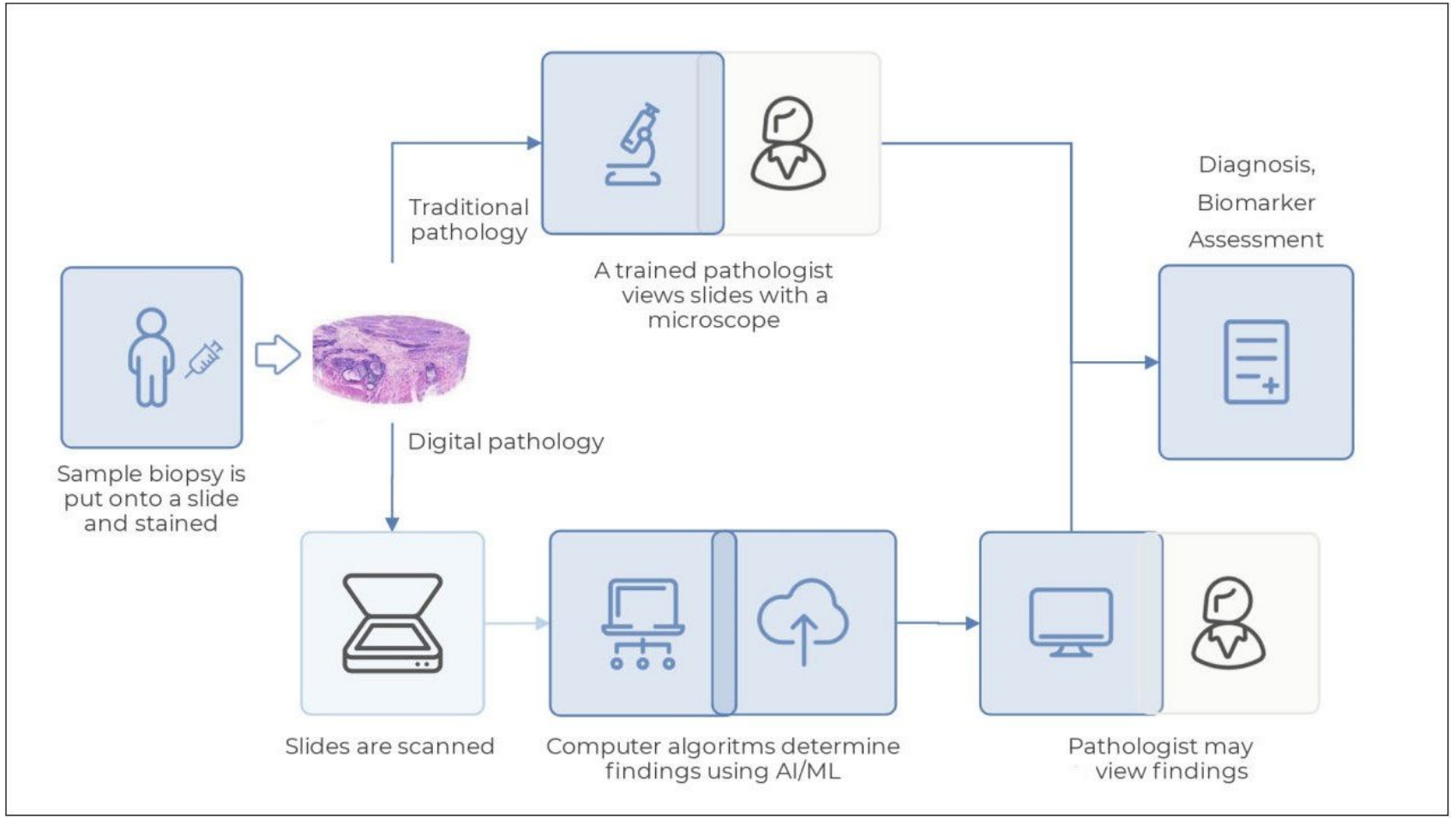
“Pathology report” the next level

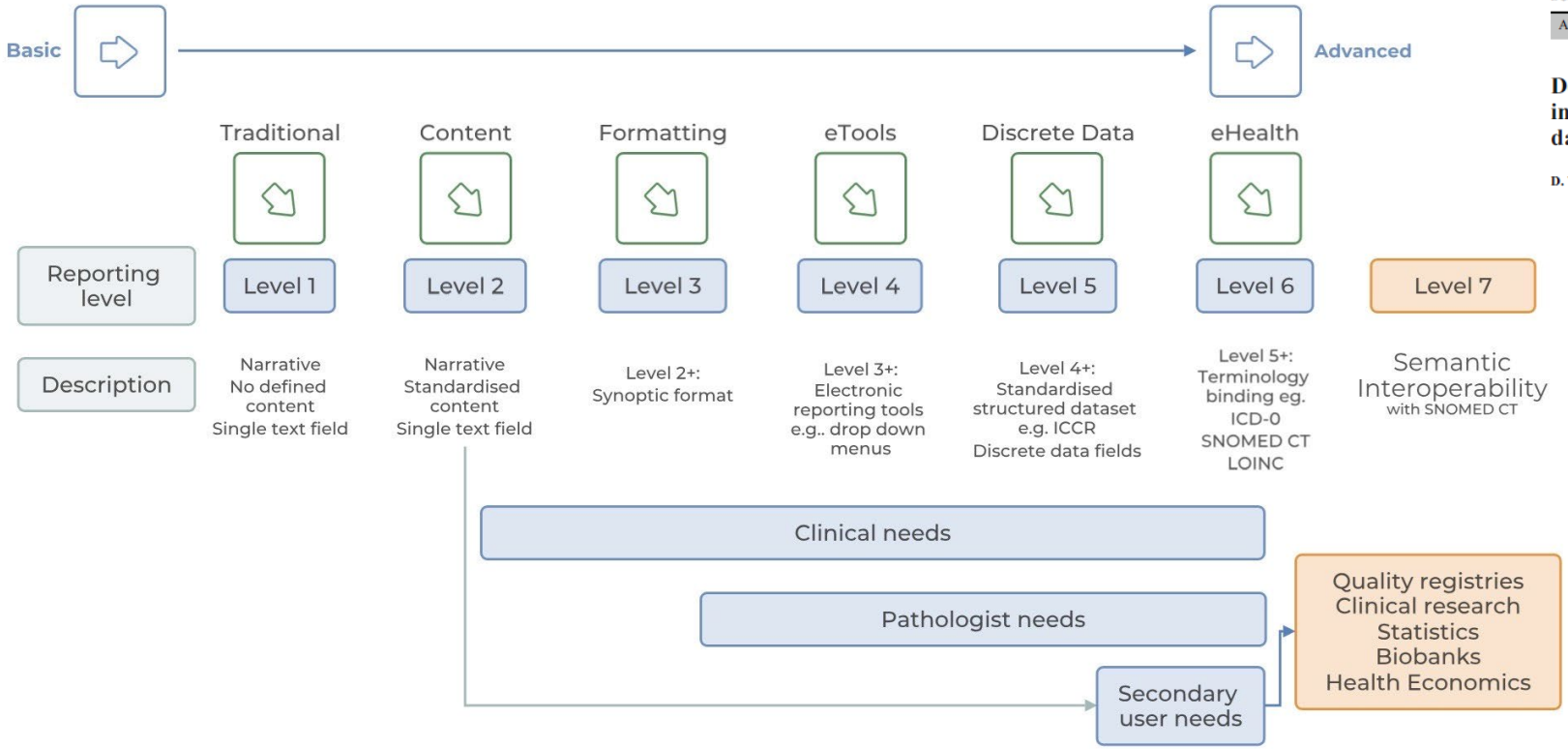


Definition of “Standardized Structured Reporting” or “Synoptic Reporting “

“Standardized Structured Reporting (SSR), also known as Synoptic Reporting (SR), is a clinical documentation method in which a standardized reporting structure helps produce more complete, consistent, accurate, and valuable medical reports.

Standardized Structured Reporting standardizes how data is collected, transmitted, stored, retrieved, and shared between clinical information systems, for primary and secondary use.”

Levels of pathology reporting
Standardized Structured Reporting (SSR) & benefits



NR = Narrative Report; SR = Synoptic Report (or Standardized Structural Report, SSR)

Virchows Arch (2016) 468:51–59
DOI 10.1007/s00428-015-1834-4

ANNUAL REVIEW ISSUE

Does standardised structured reporting contribute to quality in diagnostic pathology? The importance of evidence-based datasets

D. W. Ellis[1,2] · J. Srigley[3]

Levels 3-4+ of pathology reporting

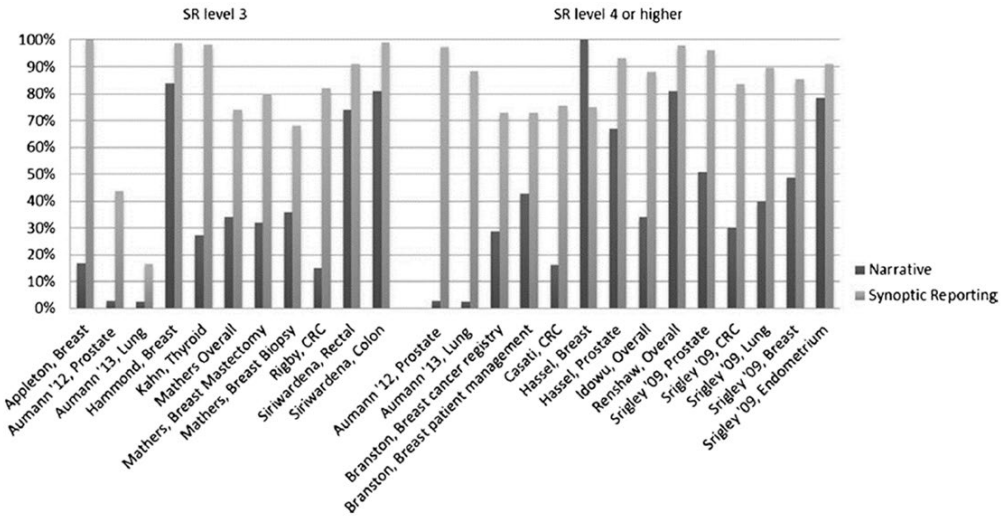
Standardized Structured Reporting (SSR) & benefits

Virchows Arch (2016) 468:639–649
DOI 10.1007/s00428-016-1935-8

REVIEW AND PERSPECTIVES

The effects of implementing synoptic pathology reporting in cancer diagnosis: a systematic review

Caro E. Sluijter[1,2] · Luc R. C. W. van Lonkhuijzen[3] · Henk-Jan van Slooten[2,4] · Iris D. Nagtegaal[1,2] · Lucy I. H. Overbeek[2]



JCO Clin Cancer Inform. 2019 May;3:1-12. doi: 10.1200/CCI.18.00104.

Improvement of Care in Patients With Colorectal Cancer: Influence of the Introduction of Standardized Structured Reporting for Pathology

Caro E Sluijter [1,2], Frans van Workum [1], Theo Wiggers [3], Carlijn van de Water [1], Otto Visser [4], Henk-Jan van Slooten [2,5], Lucy I H Overbeek [2], Iris D Nagtegaal [1,2]

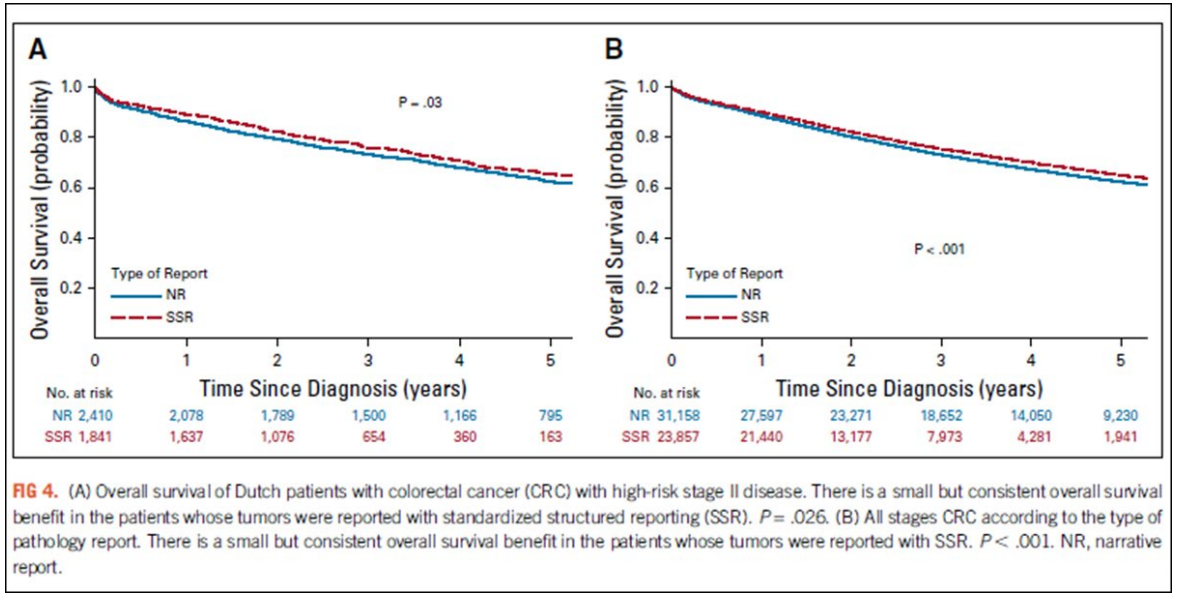
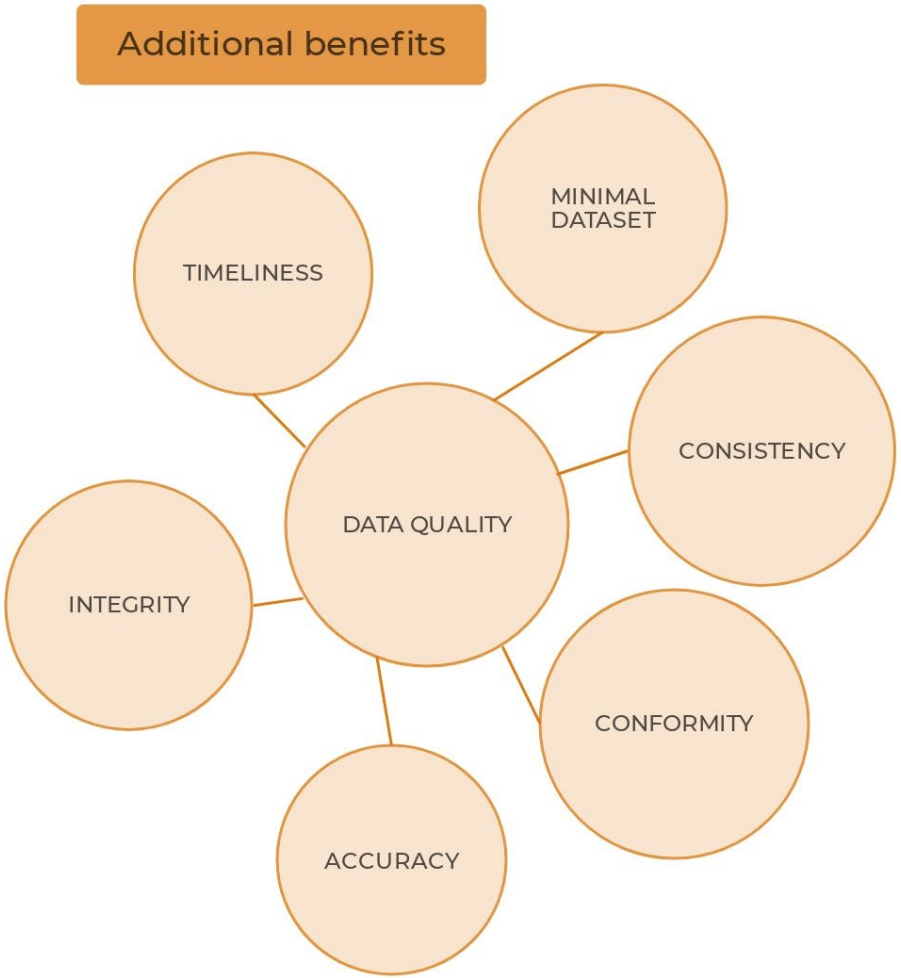


FIG 4. (A) Overall survival of Dutch patients with colorectal cancer (CRC) with high-risk stage II disease. There is a small but consistent overall survival benefit in the patients whose tumors were reported with standardized structured reporting (SSR). $P = .026$. (B) All stages CRC according to the type of pathology report. There is a small but consistent overall survival benefit in the patients whose tumors were reported with SSR. $P < .001$. NR, narrative report.

Level 5-6 of pathology reporting

Standardized Structured Reporting (SSR) & benefits



Full report

Conform (inter-)national guidelines, ICCR; WHO classifications, pTNM/FIGO/ENETS

Benchmarking (Auditing)

Quality control

E-learning support

Trial-alerts

Lowering administration burden

1. Ordering
2. Import (AI, NGS, WGS)
3. Electronic Health records (MOT)

International registries

International research

European Health Data Space (EHDS)

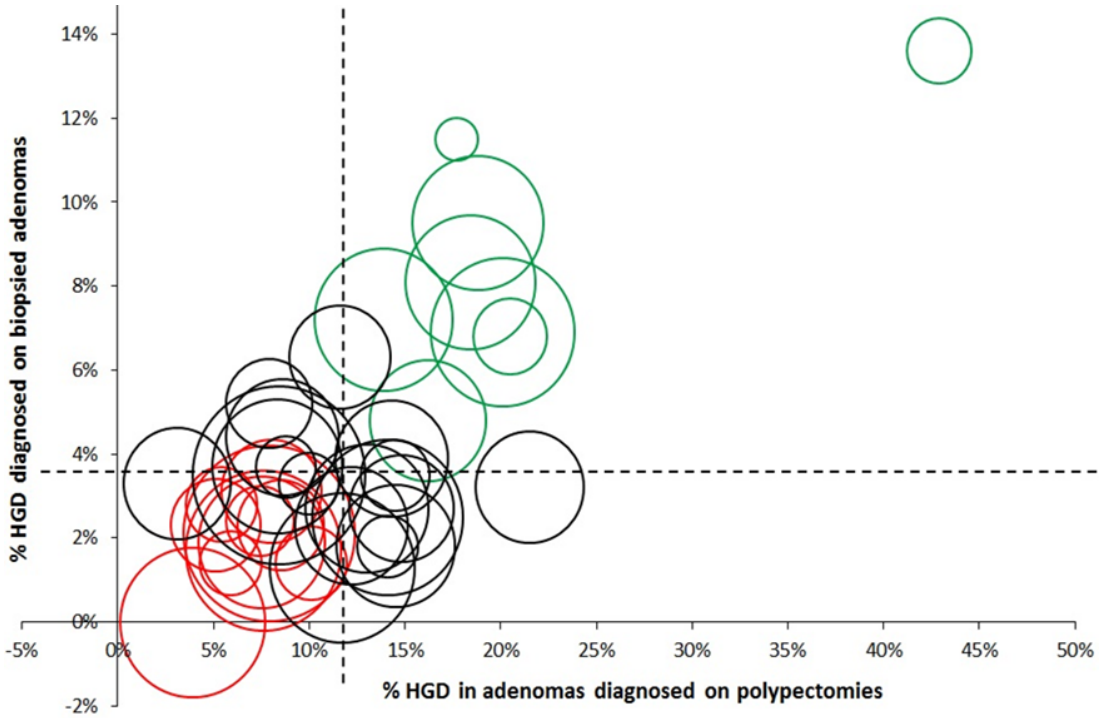
Benchmarking (Auditing)

Standardized Structured Reporting (SSR) & benefits

Histopathology 2016 DOI: 10.1111/his.12923

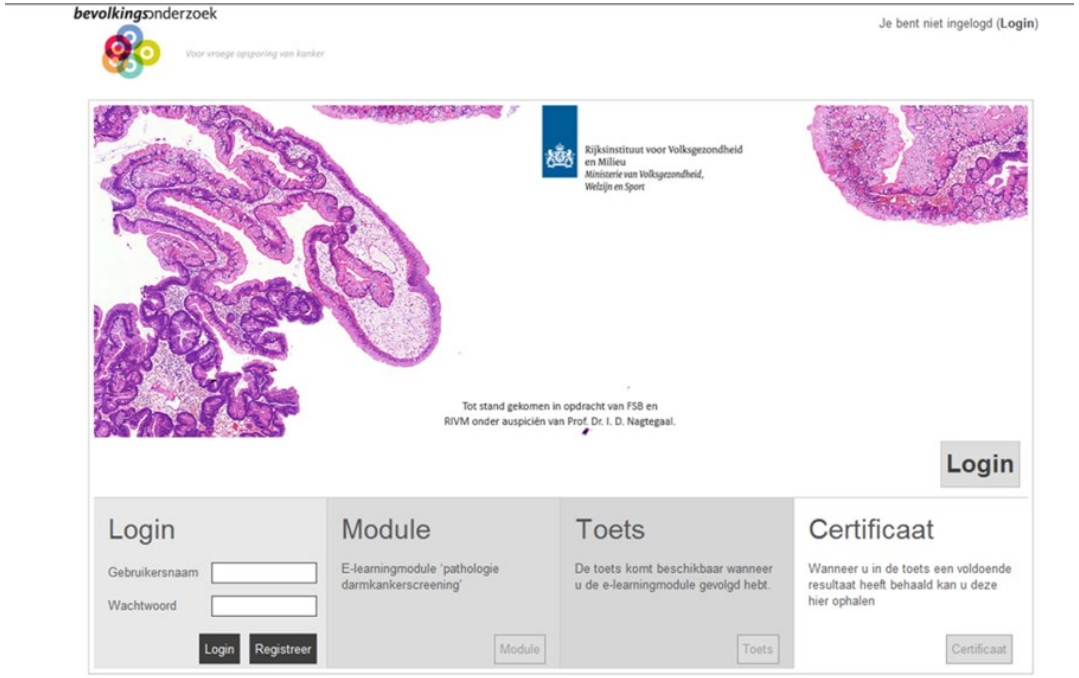
Interlaboratory variability in the grading of dysplasia in a nationwide cohort of colorectal adenomas

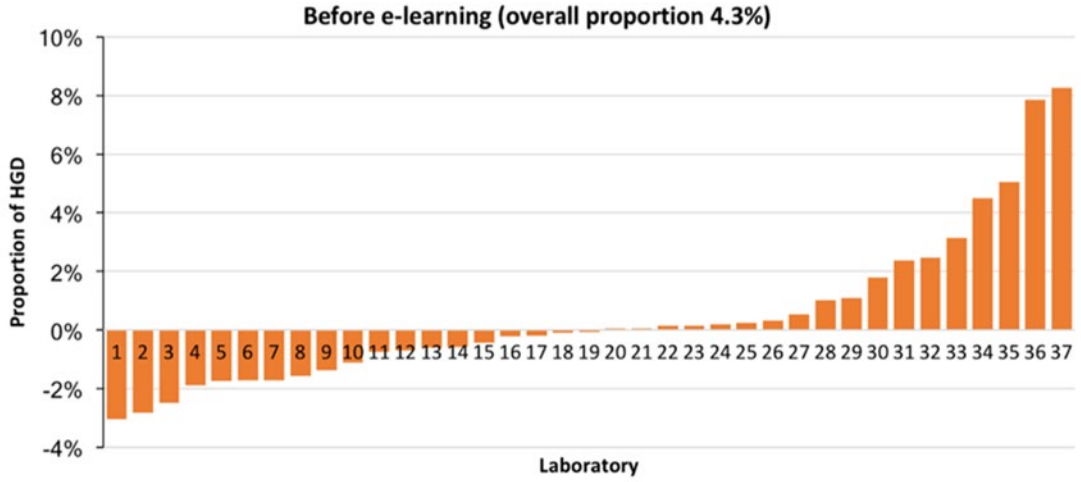
Chantal C H J Kuijpers,[1,2,3] Caro E Sluijter,[2,4] Jan H von der Thüsen,[5,6] Katrien Grünberg,[6,7] Martijn G H van Oijen,[2,8] Paul J van Diest,[1] Mehdi Jiwa,[1,3] Iris D Nagtegaal,[2,4] Lucy I H Overbeek[2] & Stefan M Willems[1,2]

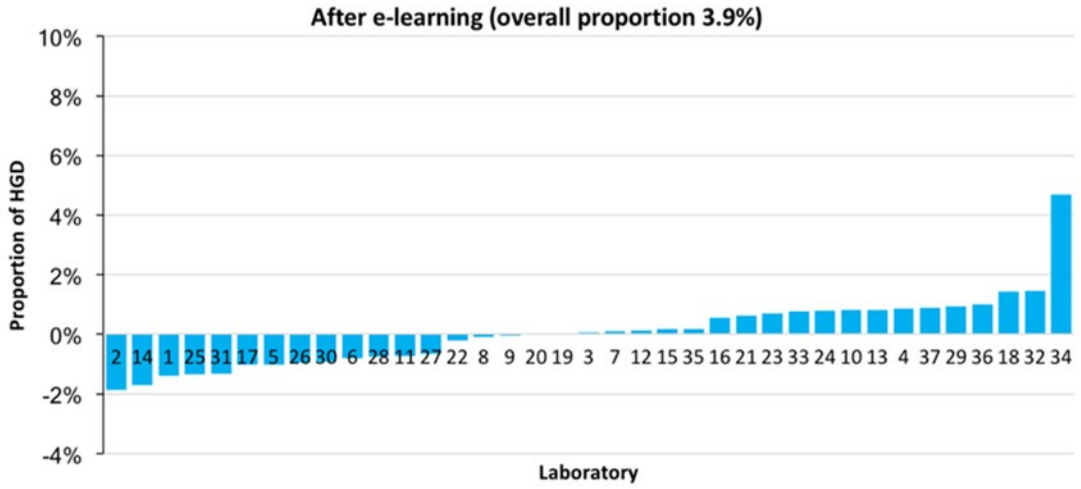


Benchmarking (Auditing)

Standardized Structured Reporting (SSR) & benefits







Interlaboratory variation of High-Grade Dysplasia in adenomas diagnosed before implementation of E-Learning (N=12,614) compared to adenomas diagnosed after implementation of E-learning (N=43,741) using national Protocol Colon-Biopsy

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Lowering administration burden / better quality data/completeness

Standardized Structured Reporting (SSR) & benefits

› Gastrointest Endosc. 2020 Jul;92(1):154-162.e1. doi: 10.1016/j.gie.2020.01.052. Epub 2020 Feb 11.

Dutch Gastrointestinal Endoscopy Audit: automated extraction of colonoscopy data for quality assessment and improvement

Michael P M de Neree Tot Babberich [1], Michiel Ledeboer [2], Monique E van Leerdam [3], Manon C W Spaander [4], Aura A J van Esch [5], Rob J Ouwendijk [6], Peter J van der Schaar [7], Sander van der Beek [8], Miangela M Lacle [9], Paul A Seegers [10], Michel W J M Wouters [11], Paul Fockens [1], Evelien Dekker [1]

Results

Between January 1, 2016 and March 31, 2019, 48 hospitals or endoscopy centers voluntarily participated in the DGEA, and 275,017 unique patients with 313,511 colonoscopies were registered. Overall missing values were limited to <1%.

Conclusions

The results of this study demonstrate that it is feasible to deploy a quality registry collecting uniform data without additional administration burden for healthcare professionals.

Saving costs are approximately €18 million per year

- National Cancer Registry (NCR)
- Population Screening Registry
  - Cervical Cancer
  - Breast Cancer
  - Bowel Cancer
- Dutch Institute for Clinical Auditing (DICA)
  - Colon Biopsy (DGEA)
  - Colon Resection (DRCA)
  - Esophagus - gastric (DUCA)
  - Lung (DSCA-L/R)
  - Pancreas (DPA)
  - Melanoma (DMTR)
  - Head-Neck Biopsy (DHNA)
  - Prostate (DPA)
  - Cervix (DGOA-cer)

Per year > 250,000 pathology data sets

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The layers of Interoperability, level 7

LAW & REGULATIONS: THE USE OF BSN; GDPR; CE-MARKING (MDR), INFORMATION SAFETY; NEN/ISO NORMS;

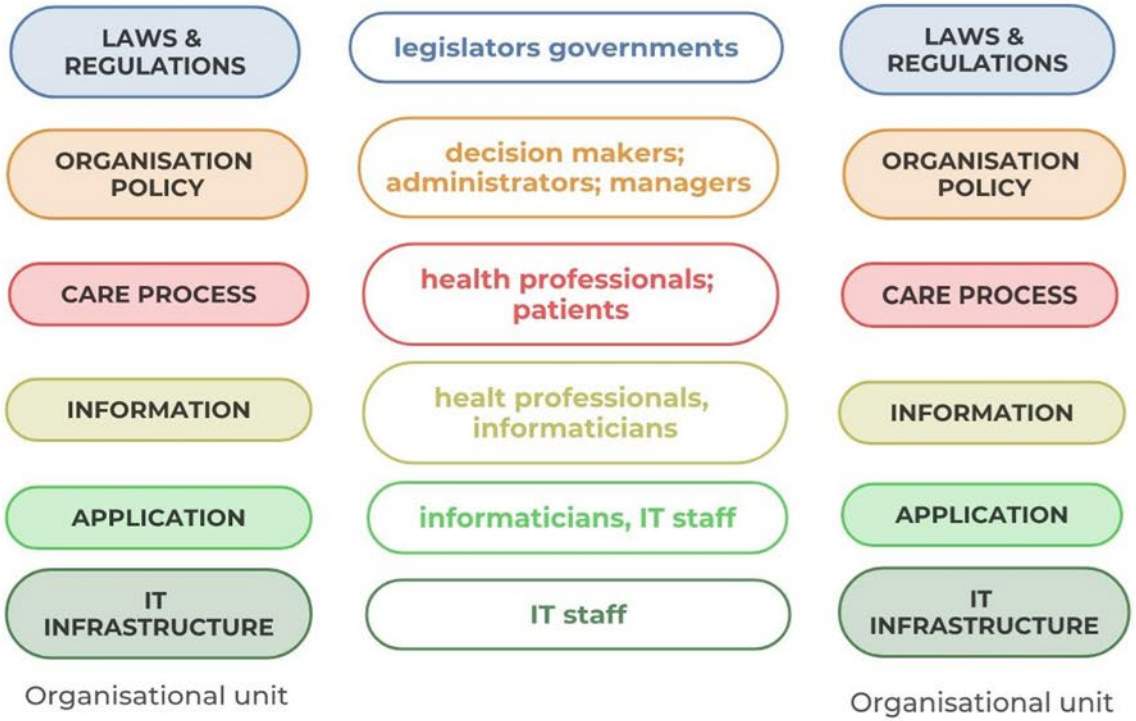
ORGANIZATION POLICY: COOPERATION AGREEMENTS WITH DIFFERENT ORGANIZATIONS; GOVERNANCE

CARE PROCESS: PROCESS AGREEMENTS AND WORKFLOW WITH DIFFERENT ORGANIZATIONS; INVOLVEMENT EXPERT GROUPS DUTCH PATHOLOGY SOCIETY; INTERDISCIPLINARY (E.G. NABON); REGISTRIES

INFORMATION: (INTERNATIONAL) STANDARDS ON PATHOLOGY (NATIONAL GUIDELINES; ICCR; TNM (AJCC & UICC); SNOMED CT

APPLICATION: PALGA PROTOCOL MODULE; STANDARDIZED NATIONAL PATHOLOGY PROTOCOLS (TEMPLETS); INTERNAL IT STAFF

IT INFRASTRUCTURE: PALGA INTERNAL INFRASTRUCTURE; SINGLE POINT CONNECTION FROM 46 LABORATORIES TO DIFFERENT REGISTRIES; INTERNAL AND EXTERNAL IT STAFF; HL7-CDA; HL7-FHIR



Law & regulations level (EU)

The layers of interoperability

Medical Device
Medical Device Coordination Group Document MDCG 2019-11

MDCG 2019-11
Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

October 2019

Medical device:
"medical device" means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

Rule 11 states:

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

death or an irreversible deterioration of a person's state of health, in which case it is in class III; or

a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software is classified as class I.

The text of Rule 11 can be divided into what are essentially three sub-rules that are applied depending on the intended use/purpose of the MDSW:

11a: (3 first paragraphs of Rule 11) intended to provide information which is used to take decisions with diagnostic or therapeutic purposes;

11b: (Paragraph 4 of Rule 11) intended to monitor physiological processes or parameters;

11c: (Paragraph 5 of Rule 11) all other uses.

Sub-rule 11a):

The wording "intended to provide information which is used to take decisions with diagnosis or therapeutic purposes" describes, in very general terms, the "mode of action" which is characteristic of all MDSW. Therefore, this sub-rule is generally applicable to all MDSW (excluding those MDSW that have no medical purpose).

Sub-rule 11a), states that MDSW (which is intended to provide information which is used to take decisions with diagnosis or therapeutic purposes) is classified as class IIa.

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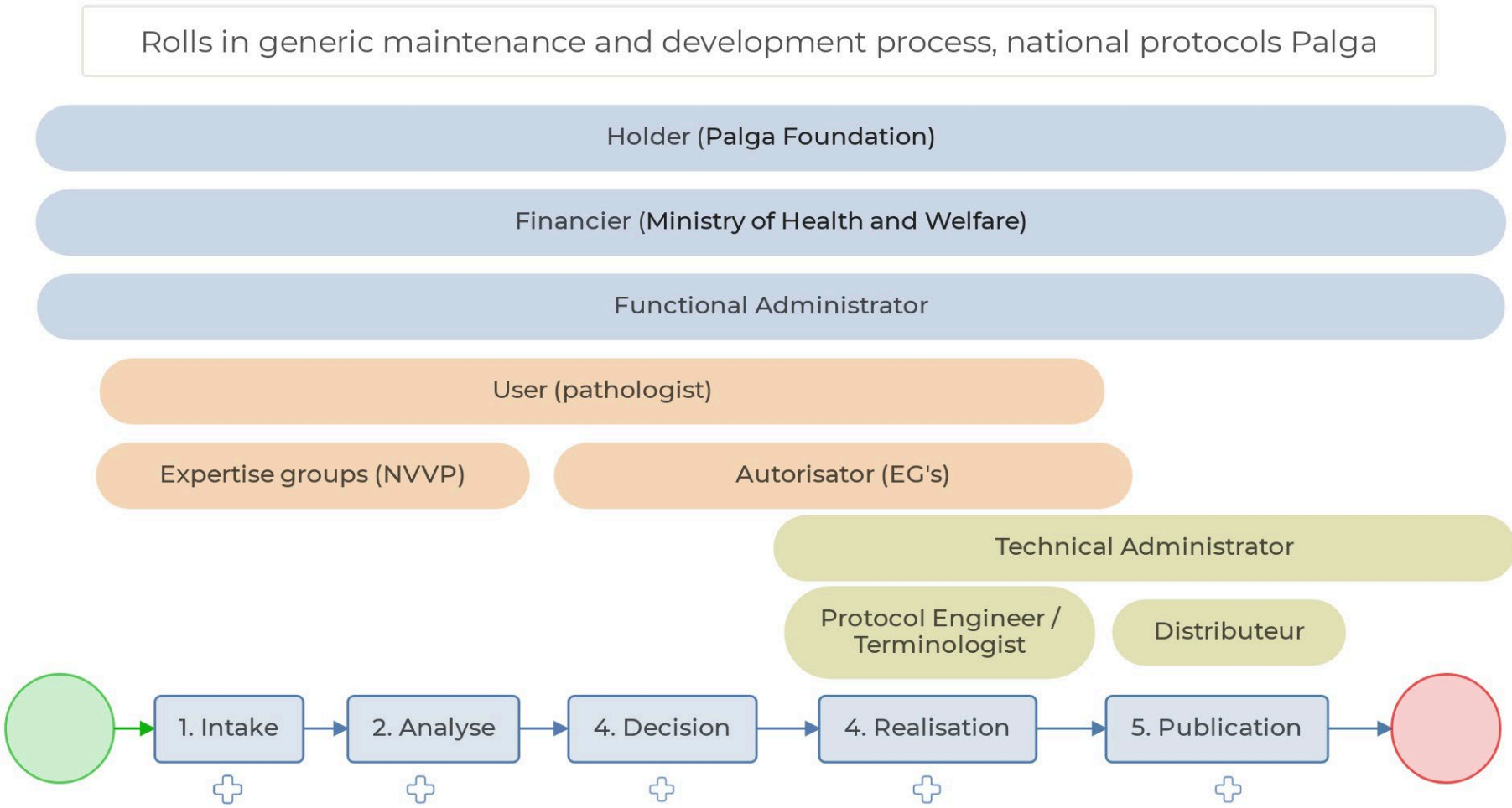
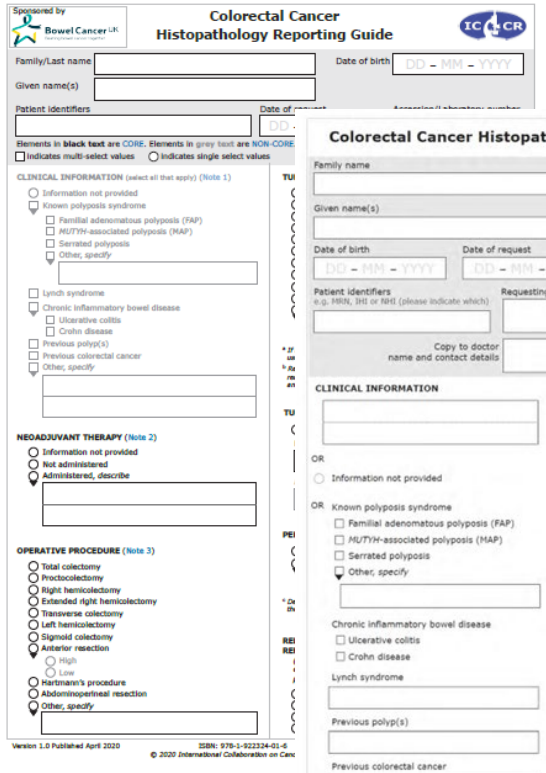
Care process level (Palga, Netherlands)

The layers of interoperability



Information level, (inter)national standards

The layers of interoperability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Colorectal Cancer Histopathology Reporting Guide

ICCR

Family/Last name

Given name(s)

Date of birth DD – MM – YYYY

Patient identifiers

Elements in **black text** are CORE, Elements in grey text are NON-CORE

Indicates multi-select values Indicates single select values

CLINICAL INFORMATION (select all that apply) (Note 1)

Information not provided

Known polyposis syndrome

Familial adenomatous polyposis (FAP)

MUTYH-associated polyposis (MAP)

Serrated polyposis

Other, specify

Lynch syndrome

Chronic inflammatory bowel disease

Ulcerative colitis

Crohn disease

Previous polyp(s)

Previous colorectal cancer

Other, specify

NEOADJUVANT THERAPY (Note 2)

Information not provided

Not administered

Administered, describe

OPERATIVE PROCEDURE (Note 3)

Total colectomy

Proctocolectomy

Right hemicolectomy

Extended right hemicolectomy

Transverse colectomy

Left hemicolectomy

Sigmoid colectomy

Anterior resection

High

Low

Hartmann's procedure

Abdominoperineal resection

Other, specify

Version 1.0 Published April 2020 ISBN: 978-1-922324-01-6

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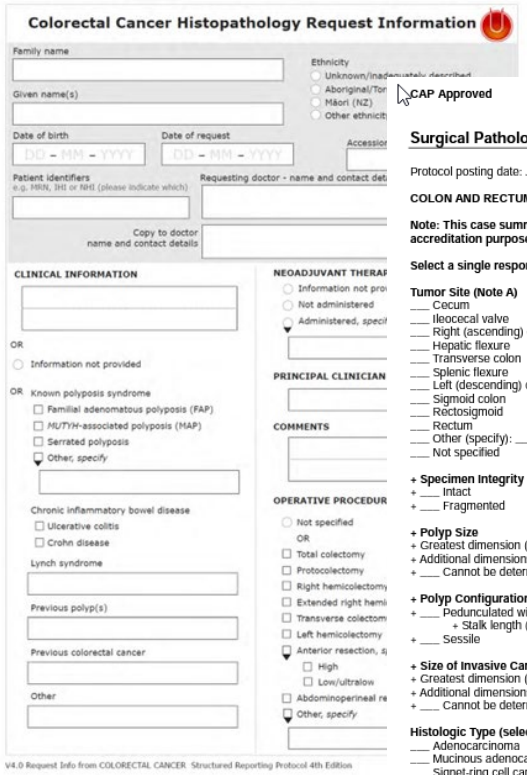

Colorectal Cancer Histopathology Request Information

Family name

Given name(s)

Date of birth Date of request

Patient identifiers

e.g. MRN, IHI or NHI (please indicate which)

Requesting doctor - name and contact details

Copy to doctor name and contact details

Ethnicity

Unknown/inadequately described

Aboriginal/Tor

Māori (NZ)

Other ethnicit

CLINICAL INFORMATION

Information not provided

OR

Known polyposis syndrome

Familial adenomatous polyposis (FAP)

MUTYH-associated polyposis (MAP)

Serrated polyposis

Other, specify

Chronic inflammatory bowel disease

Ulcerative colitis

Crohn disease

Lynch syndrome

Previous polyp(s)

Previous colorectal cancer

Other

NEOADJUVANT THERAP

Information not pro

Not administered

Administered, specif

PRINCIPAL CLINICIAN

COMMENTS

OPERATIVE PROCEDUR

Not specified

OR

Total colectomy

Protocolectomy

Right hemicolectomy

Extended right hemi

Transverse colectom

Left hemicolectomy

Anterior resection, s

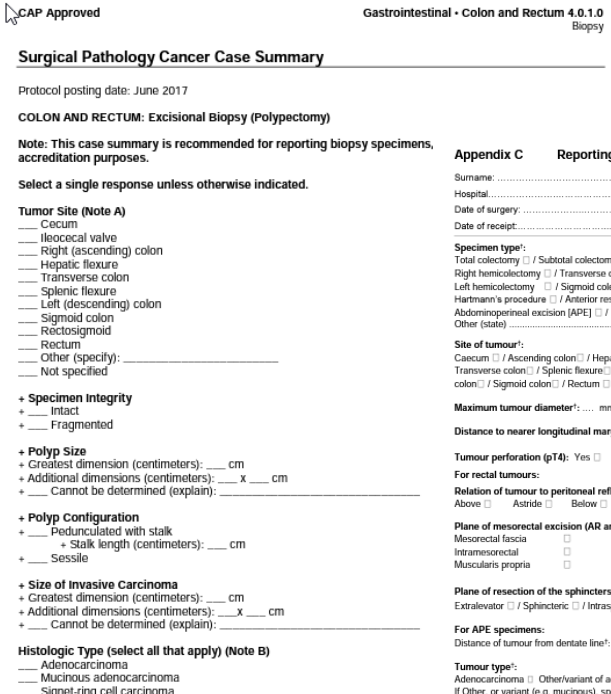
High

Low/ultralow

Abdominoperineal re

Other, specify

V4.0 Request Info from COLORECTAL CANCER Structured Reporting Protocol 4th Edition


CAP Approved

Gastrointestinal • Colon and Rectum 4.0.1.0

Biopsy

Surgical Pathology Cancer Case Summary

Protocol posting date: June 2017

COLON AND RECTUM: Excisional Biopsy (Polypectomy)

Note: This case summary is recommended for reporting biopsy specimens, accreditation purposes.

Select a single response unless otherwise indicated.

Tumor Site (Note A)

___ Cecum
___ Ileocecal valve
___ Right (ascending) colon
___ Hepatic flexure
___ Transverse colon
___ Splenic flexure
___ Left (descending) colon
___ Sigmoid colon
___ Rectosigmoid
___ Rectum
___ Other (specify): _____
___ Not specified

+ Specimen Integrity

+ ___ Intact
+ ___ Fragmented

+ Polyp Size

+ Greatest dimension (centimeters): ___ cm
+ Additional dimensions (centimeters): ___ x ___ cm
+ ___ Cannot be determined (explain): _____

+ Polyp Configuration

+ ___ Pedunculated with stalk
  + Stalk length (centimeters): ___ cm
+ ___ Sessile

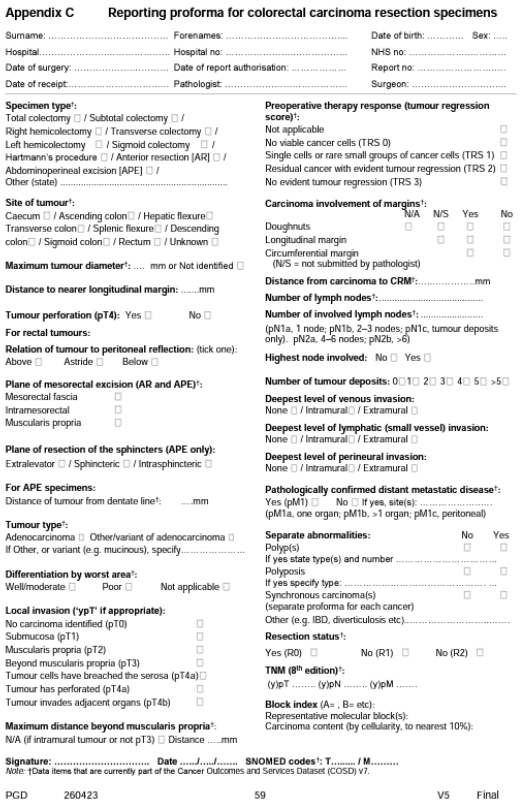
+ Size of Invasive Carcinoma

+ Greatest dimension (centimeters): ___ cm
+ Additional dimensions (centimeters): ___x ___ cm
+ ___ Cannot be determined (explain): _____

Histologic Type (select all that apply) (Note B)

___ Adenocarcinoma
___ Mucinous adenocarcinoma
___ Signet-ring cell carcinoma
___ Medullary carcinoma
___ Micropapillary carcinoma
___ Serrated adenocarcinoma
___ Large cell neuroendocrine carcinoma
___ Small cell neuroendocrine carcinoma
___ Neuroendocrine carcinoma (poorly differentiated)#
___ Squamous cell carcinoma

+ Data elements preceded by this symbol are not required for accreditation purposes. These option clinically important but are not yet validated or regularly used in patient management.


Appendix C Reporting proforma for colorectal carcinoma resection specimens

Surname: ..... Forenames: ..... Date of birth: ..... Sex: .....

Hospital..... Hospital no: ..... NHS no: .....

Date of surgery: ..... Date of report authorisation: ..... Report no: .....

Date of receipt:..... Pathologist: ..... Surgeon: .....

Specimen type†:
Total colectomy ☐ / Subtotal colectomy ☐ /
Right hemicolectomy ☐ / Transverse colectomy ☐ /
Left hemicolectomy ☐ / Sigmoid colectomy ☐ /
Hartmann's procedure ☐ / Anterior resection [AR] ☐ /
Abdominoperineal excision [APE] ☐ /
Other (state) .....

Site of tumour†:
Caecum ☐ / Ascending colon☐ / Hepatic flexure☐
Transverse colon☐ / Splenic flexure☐ / Descending colon☐ / Sigmoid colon☐ / Rectum ☐ / Unknown ☐

Maximum tumour diameter†: .... mm or Not identified ☐

Distance to nearer longitudinal margin: .....mm

Tumour perforation (pT4): Yes ☐ No ☐

For rectal tumours:

Relation of tumour to peritoneal reflection: (tick one):
Above ☐ Astride ☐ Below ☐

Plane of mesorectal excision (AR and APE)†:
Mesorectal fascia ☐
Intramesorectal ☐
Muscularis propria ☐

Plane of resection of the sphincters (APE only):
Extralevator ☐ / Sphincteric ☐ / Intrasphincteric ☐

For APE specimens:
Distance of tumour from dentate line†: ....mm

Tumour type†:
Adenocarcinoma ☐ Other/variant of adenocarcinoma ☐
If Other, or variant (e.g. mucinous), specify.....

Differentiation by worst area†:
Well/moderate ☐ Poor ☐ Not applicable ☐

Local invasion ('ypT' if appropriate):
No carcinoma identified (pT0) ☐
Submucosa (pT1) ☐
Muscularis propria (pT2) ☐
Beyond muscularis propria (pT3) ☐
Tumour cells have breached the serosa (pT4a)☐
Tumour has perforated (pT4a) ☐
Tumour invades adjacent organs (pT4b) ☐

Maximum distance beyond muscularis propria†:
N/A (if intramural tumour or not pT3) ☐ Distance .....mm

Preoperative therapy response (tumour regression score)†:
Not applicable ☐
No viable cancer cells (TRS 0) ☐
Single cells or rare small groups of cancer cells (TRS 1) ☐
Residual cancer with evident tumour regression (TRS 2) ☐
No evident tumour regression (TRS 3) ☐

Carcinoma involvement of margins†:

	N/A	N/S	Yes	No
Doughnuts	☐	☐	☐	☐
Longitudinal margin		☐	☐	☐
Circumferential margin (N/S = not submitted by pathologist)		☐	☐	☐

Distance from carcinoma to CRM†:.....mm

Number of lymph nodes†:.....

Number of involved lymph nodes†:.....
(pN1a, 1 node; pN1b, 2–3 nodes; pN1c, tumour deposits only). pN2a, 4–6 nodes; pN2b, >6)

Highest node involved: No ☐ Yes ☐

Number of tumour deposits: 0☐1☐ 2☐ 3☐ 4☐ 5☐ >5☐

Deepest level of venous invasion:
None ☐ / Intramural☐ / Extramural ☐

Deepest level of lymphatic (small vessel) invasion:
None ☐ / Intramural☐ / Extramural ☐

Deepest level of perineural invasion:
None ☐ / Intramural☐ / Extramural ☐

Pathologically confirmed distant metastatic disease†:
Yes (pM1) ☐ No ☐ If yes, site(s): .....
(pM1a, one organ; pM1b, >1 organ; pM1c, peritoneal)

Separate abnormalities:	No	Yes
Polyp(s)	☐	☐
If yes state type(s) and number		
Polyposis	☐	☐
If yes specify type:		
Synchronous carcinoma(s) (separate proforma for each cancer)	☐	☐

Other (e.g. IBD, diverticulosis etc).....

Resection status†:
Yes (R0) ☐ No (R1) ☐ No (R2) ☐

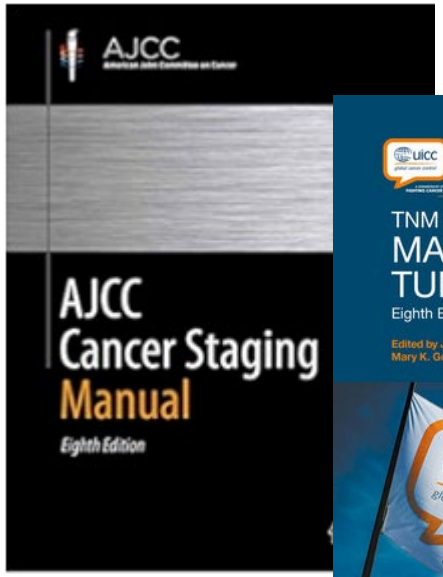
TNM (8th edition)†:
(y)pT ..... (y)pN ..... (y)pM .....

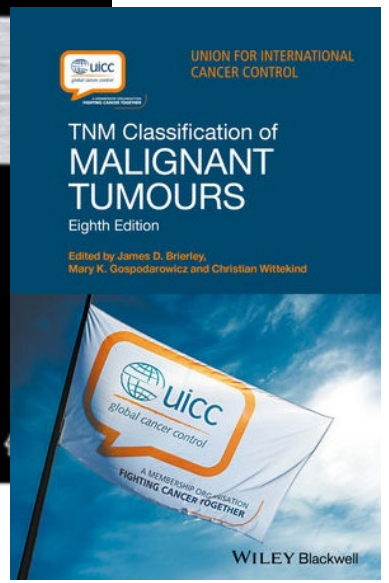
Block index (A= , B= etc):
Representative molecular block(s):
Carcinoma content (by cellularity, to nearest 10%):

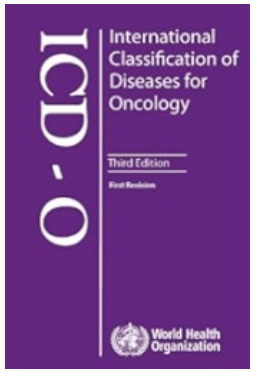
Signature: ..... **Date** ...../...../..... **SNOMED codes†: T**..... **/ M**.....

Note: †Data items that are currently part of the Cancer Outcomes and Services Dataset (COSD) v7.

PGD 260423 59 V5 Final







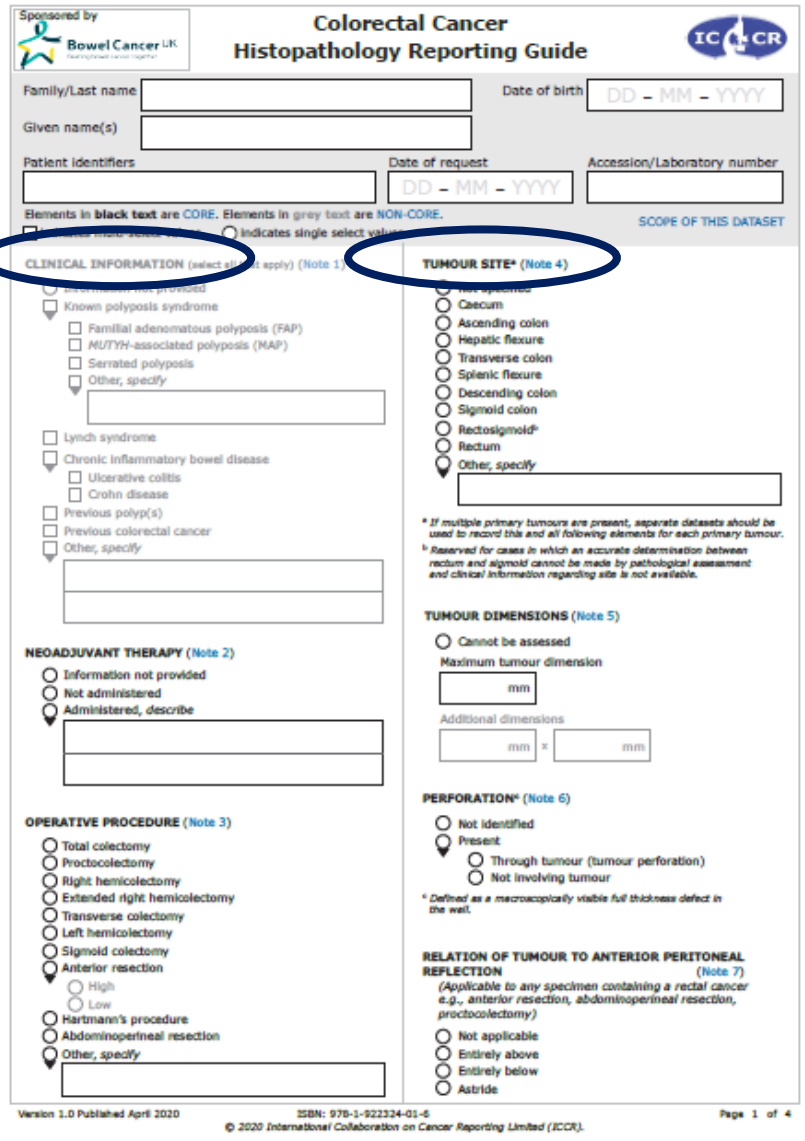
LOINC®
from Regenstrief

SNOMED International
Delivering SNOMED CT

palga

Information level, international standard (ICCR example) Level 3+

The layers of interoperability



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Colorectal Cancer Histopathology Reporting Guide

ICCR

Family/Last name | Date of birth DD – MM – YYYY

Given name(s)

Patient identifiers | Date of request DD – MM – YYYY | Accession/Laboratory number

Elements in **black text** are CORE. Elements in grey text are NON-CORE.

SCOPE OF THIS DATASET

CLINICAL INFORMATION (select all that apply) (Note 1)

- Information not provided
- Known polyposis syndrome
  - Familial adenomatous polyposis (FAP)
  - *MUTYH*-associated polyposis (MAP)
  - Serrated polyposis
  - Other, specify
- Lynch syndrome
- Chronic inflammatory bowel disease
  - Ulcerative colitis
  - Crohn disease
- Previous polyp(s)
- Previous colorectal cancer
- Other, specify

NEOADJUVANT THERAPY (Note 2)

- Information not provided
- Not administered
- Administered, describe

OPERATIVE PROCEDURE (Note 3)

- Total colectomy
- Proctocolectomy
- Right hemicolectomy
- Extended right hemicolectomy
- Transverse colectomy
- Left hemicolectomy
- Sigmoid colectomy
- Anterior resection
  - High
  - Low
- Hartmann's procedure
- Abdominoperineal resection
- Other, specify

TUMOUR SITE[a] (Note 4)

- Caecum
- Ascending colon
- Hepatic flexure
- Transverse colon
- Splenic flexure
- Descending colon
- Sigmoid colon
- Rectosigmoid[b]
- Rectum
- Other, specify

[a] *If multiple primary tumours are present, separate datasets should be used to record this and all following elements for each primary tumour.*

[b] *Reserved for cases in which an accurate determination between rectum and sigmoid cannot be made by pathological assessment and clinical information regarding site is not available.*

TUMOUR DIMENSIONS (Note 5)

- Cannot be assessed

Maximum tumour dimension: mm

Additional dimensions: mm × mm

PERFORATION[c] (Note 6)

- Not identified
- Present
  - Through tumour (tumour perforation)
  - Not involving tumour

[c] *Defined as a macroscopically visible full thickness defect in the wall.*

RELATION OF TUMOUR TO ANTERIOR PERITONEAL REFLECTION (Note 7)

(Applicable to any specimen containing a rectal cancer e.g., anterior resection, abdominoperineal resection, proctocolectomy)

- Not applicable
- Entirely above
- Entirely below
- Astride

Version 1.0 Published April 2020 ISBN: 978-1-922324-01-6 Page 1 of 4

CORE elements

Core elements are essential for the cancer's clinical management, staging, or prognosis. These elements will have evidentiary support at Level III-2 or above (based on prognostic factors in the National Health and Medical Research Council (NHMRC)). In rare circumstances, where level III-2 evidence is not available, an element may be made a core element where there is unanimous agreement in the Dataset Authoring Committee (DAC).

Non-CORE elements

Non-core elements are unanimously agreed to be included in the dataset but are not supported by level III-2 evidence. These elements may be clinically important and recommended as good practice but are not validated or regularly used in patient management.

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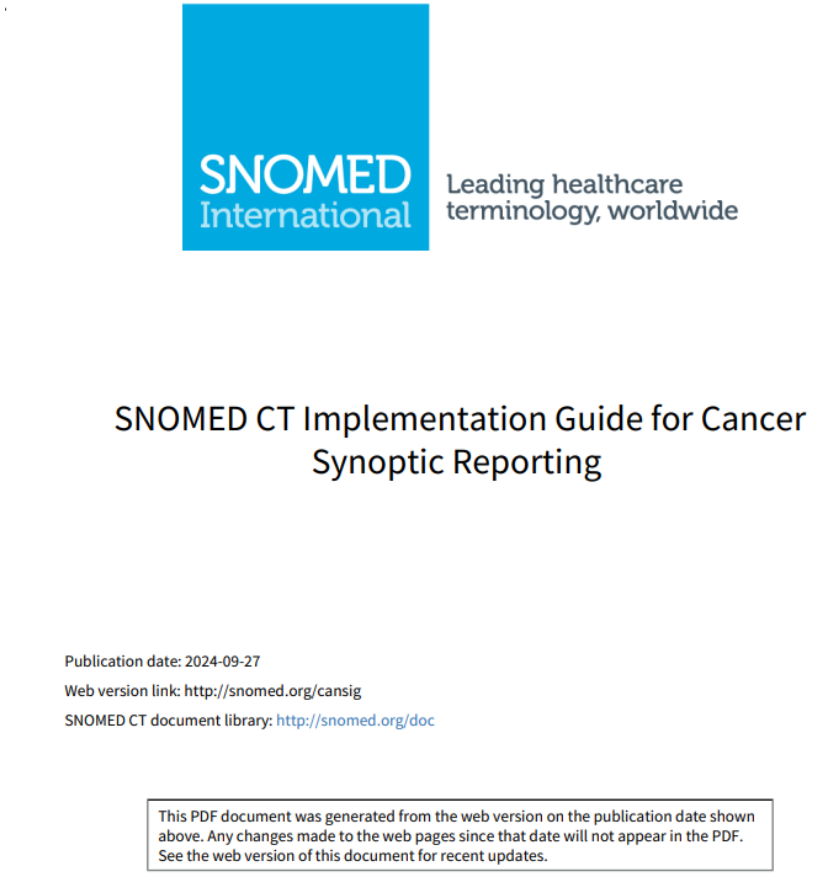
Information level, international standard SNOMED-CT Level 7

The layers of interoperability

- The purpose of this SNOMED CT Implementation Guide for Cancer Synoptic Reporting is to provide a structured and comprehensive roadmap for the implementation of SNOMED CT in this field.
- The guide covers topics important for the implementation of clinical information systems facilitating high-quality, consistent and meaningful use of SNOMED CT in cancer synoptic reporting.
- By adopting SNOMED CT, healthcare organizations can improve patient care, facilitate research, and promote collaboration between healthcare providers.
- Targeted at both clinical users and technical implementers, this Implementation Guide will provide the necessary resources and guidance to ensure a successful SNOMED CT implementation in the field of cancer synoptic reporting



An Initiative for Collaboration Between SNOMED International & ICCR

Why this initiative?

- Mutual benefit for the use of SNOMED CT bindings in International datasets for pathology
  - To use as training sets for SNOMED International
  - To use when implementing Synoptic Reporting in a national pathology community as a reference
  - It will promote interoperability, national and international

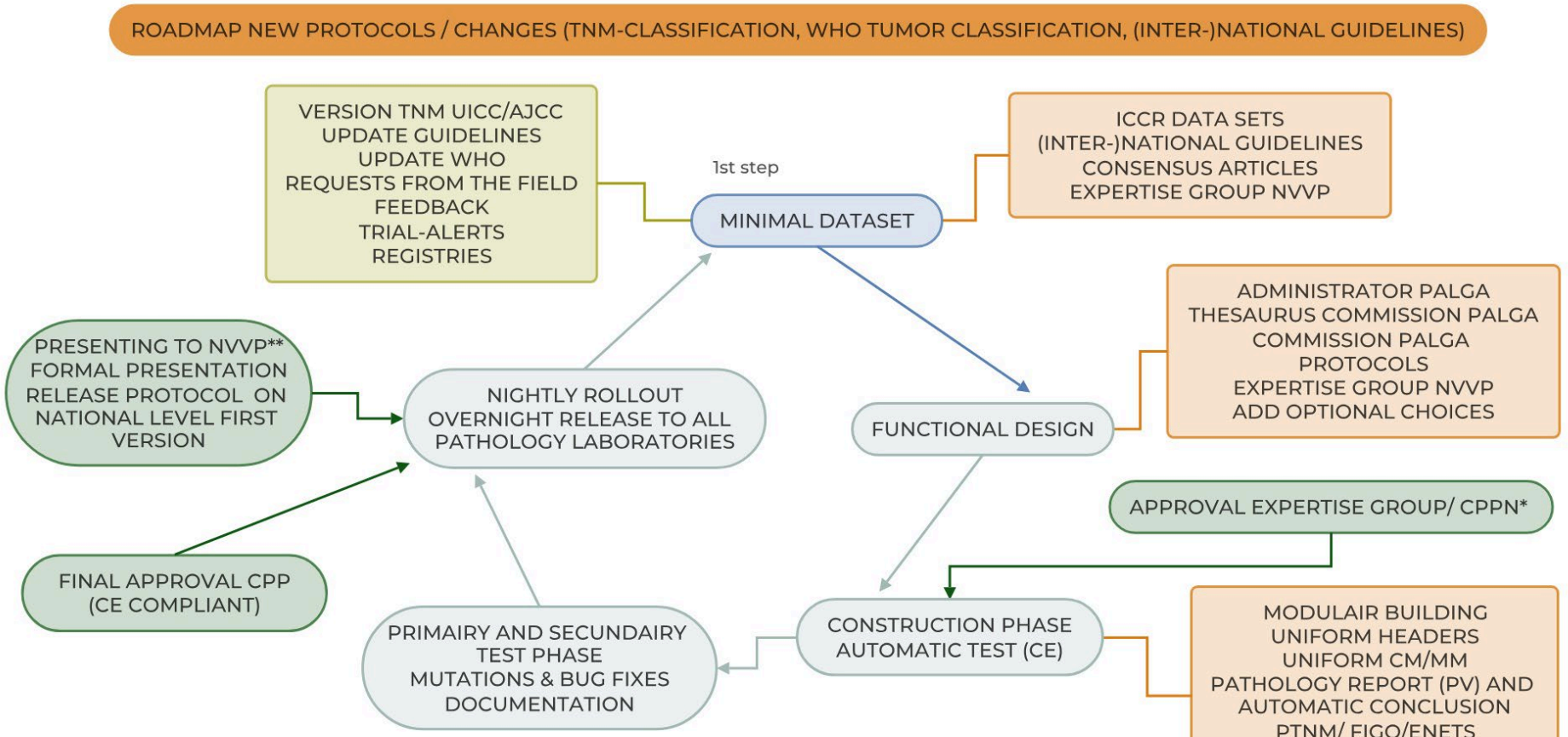
Core and Non-core	OPERATIVE PROCEDURE	o Total colectomy o Proctocolectomy o Right hemicolectomy o Extended right hemicolectomy o Transverse colectomy o Left hemicolectomy o Sigmoid colectomy o Anterior resection o High o Low o Hartmann's procedure o Abdominoperineal resection o Other, *specify*	

Question SCT	Answer item	Answer SCT
2620001000004108 |Specimen collection procedure (observable entity)|	Total colectomy	26390003 |Total colectomy (procedure)|
2620001000004108 |Specimen collection procedure (observable entity)|	Proctocolectomy	174059005 |Excision of colon and rectum (procedure)|
2620001000004108 |Specimen collection procedure (observable entity)|	Right hemicolectomy	359571009 |Right colectomy (procedure)|
2620001000004108 |Specimen collection procedure (observable entity)|	Extended right hemicolectomy	174071004 |Extended right hemicolectomy (procedure)|
2620001000004108 |Specimen collection procedure (observable entity)|	Transverse colectomy	26925005 |Transverse colectomy (procedure)|
2620001000004108 |Specimen collection procedure (observable entity)|	Left hemicolectomy	82619000 |Left colectomy (procedure)|
2620001000004108 |Specimen collection procedure (observable entity)|	Sigmoid colectomy	84604002 |Sigmoid colectomy (procedure)|
2620001000004108 |Specimen collection procedure (observable entity)|	Anterior resection	4558008 |Anterior resection of rectum (procedure)|
2620001000004108 |Specimen collection	High	400988008 |High anterior resection of

ISBN: 978 1 922324 01 6 – published April 2020

Application level (procedure Palga, Netherlands)

The layers of interoperability



***CPPN = Commission Protocols PPM NVVP**
**** NVVP = Dutch Pathology Society (NVVP)**

IT infrastructure level (Palga, Netherlands)

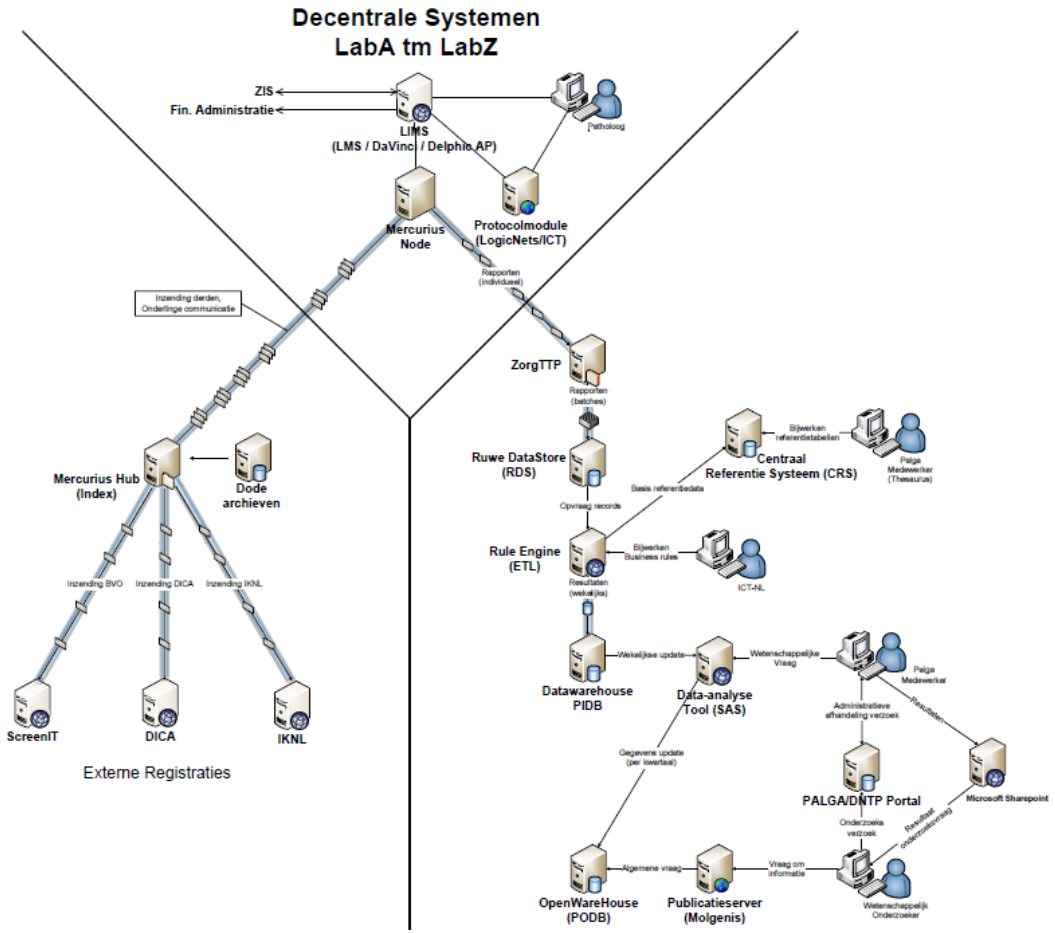
The layers of interoperability

Decentral part Mercurius node for

- Connection with LIS
- Connection with PPM

Central part for:

- Patient history for direct
- Registries



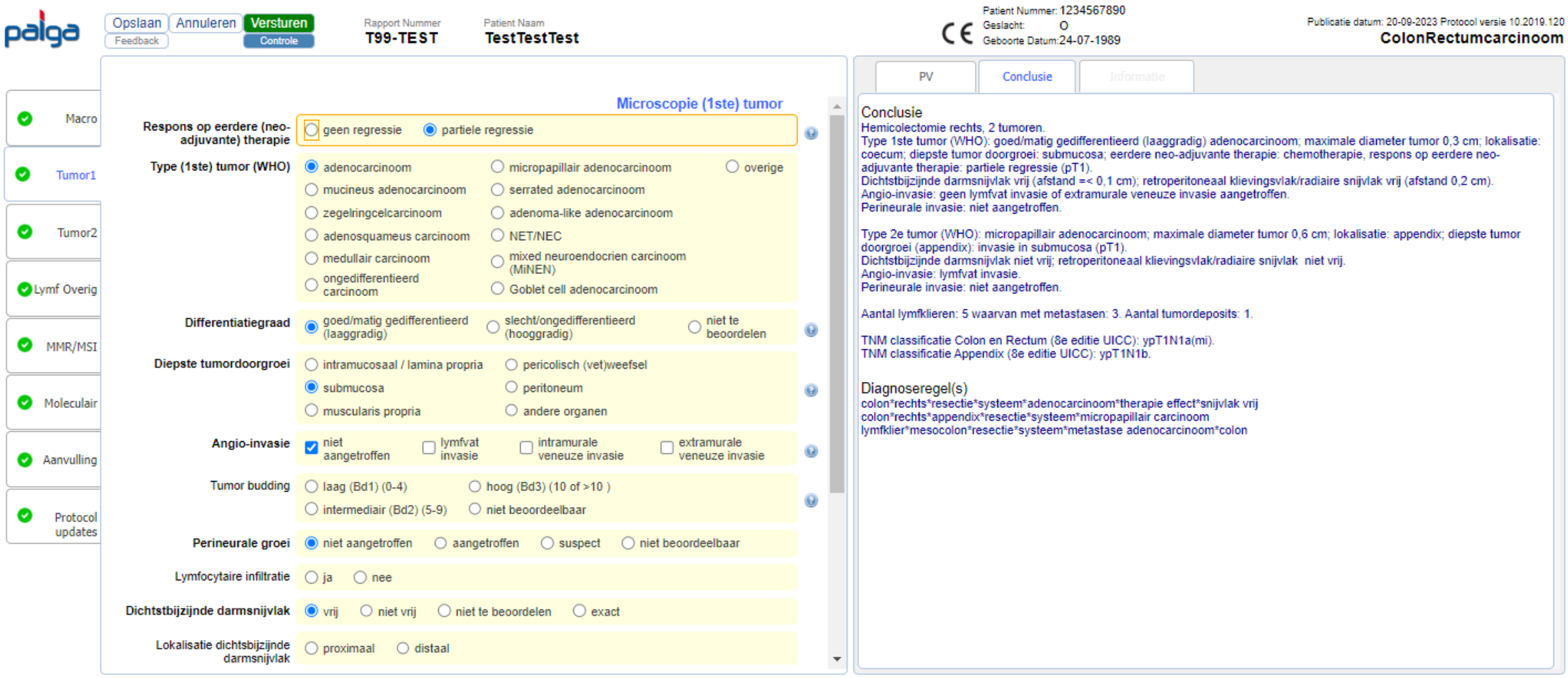
Intranet Lab2Lab connection between alle Pathology Laboratories

Scientific national part for:

- Research

Level 6 of pathology reporting (Palga, Netherlands)

The layers of interoperability



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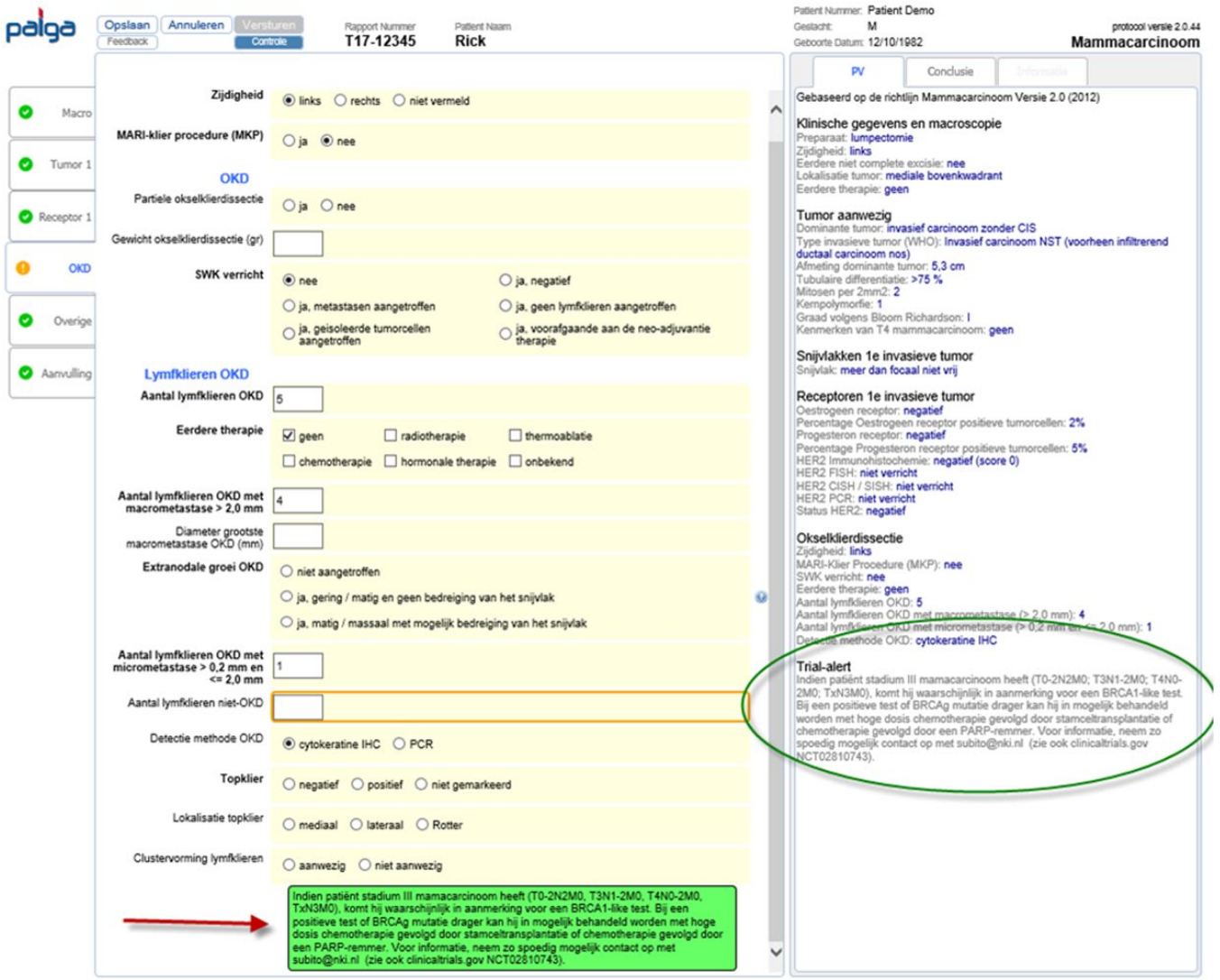
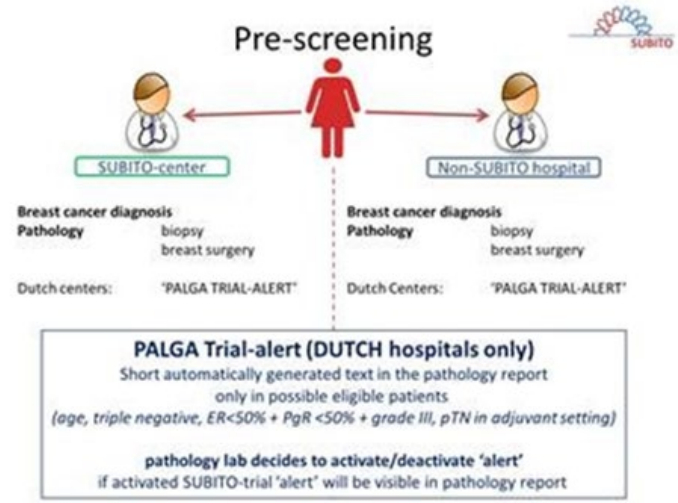
Level 6 of pathology reporting, trial alerts (Palga, Netherlands)

The layers of interoperability





Breast trials:
Tailored Treatment in Older Patients TOP-1: Omission of radiotherapy in elderly patients with low-risk breast cancer

BOOG23:
Omitting Sentinel Node Procedure in Breast Cancer Patients Undergoing Breast Conserving Therapy

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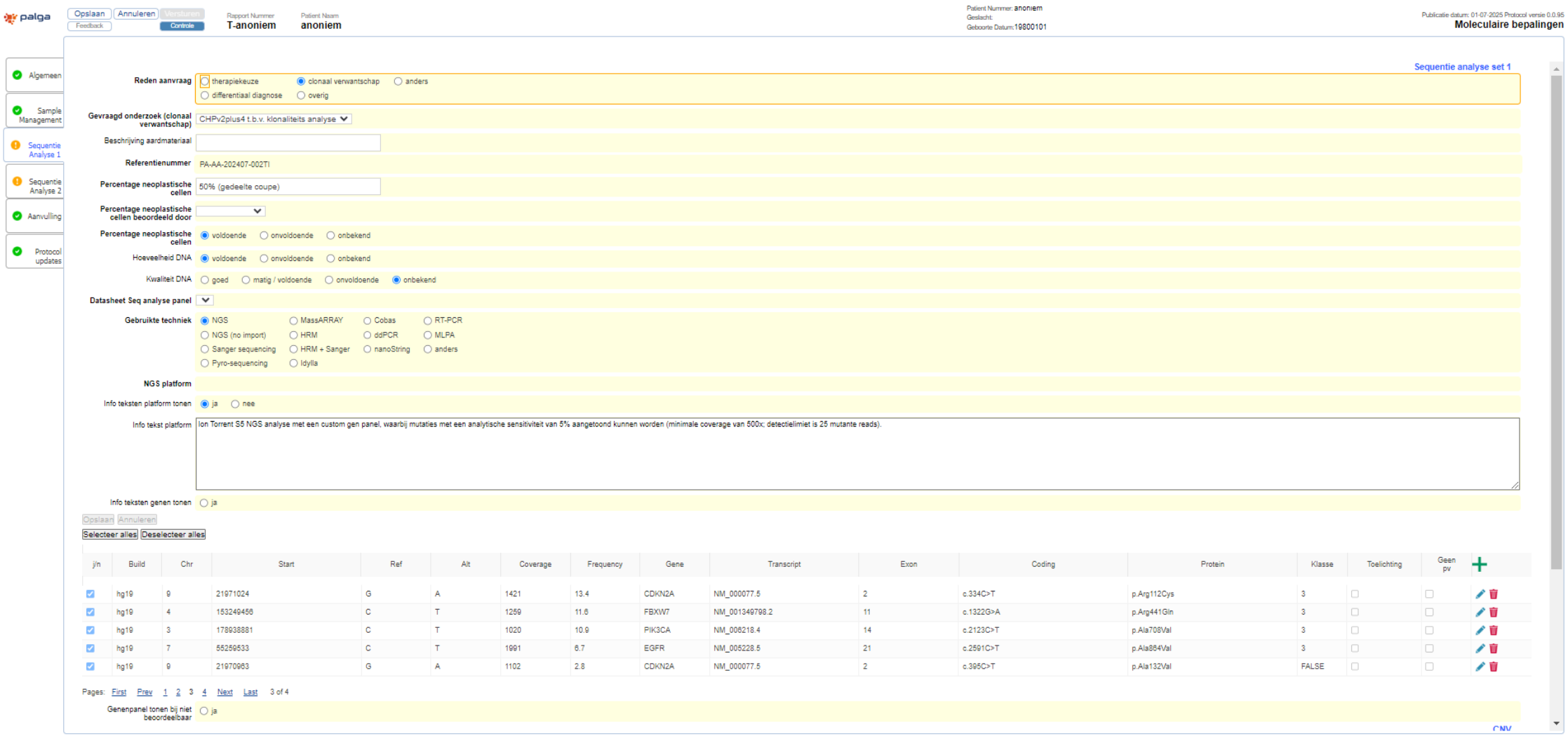
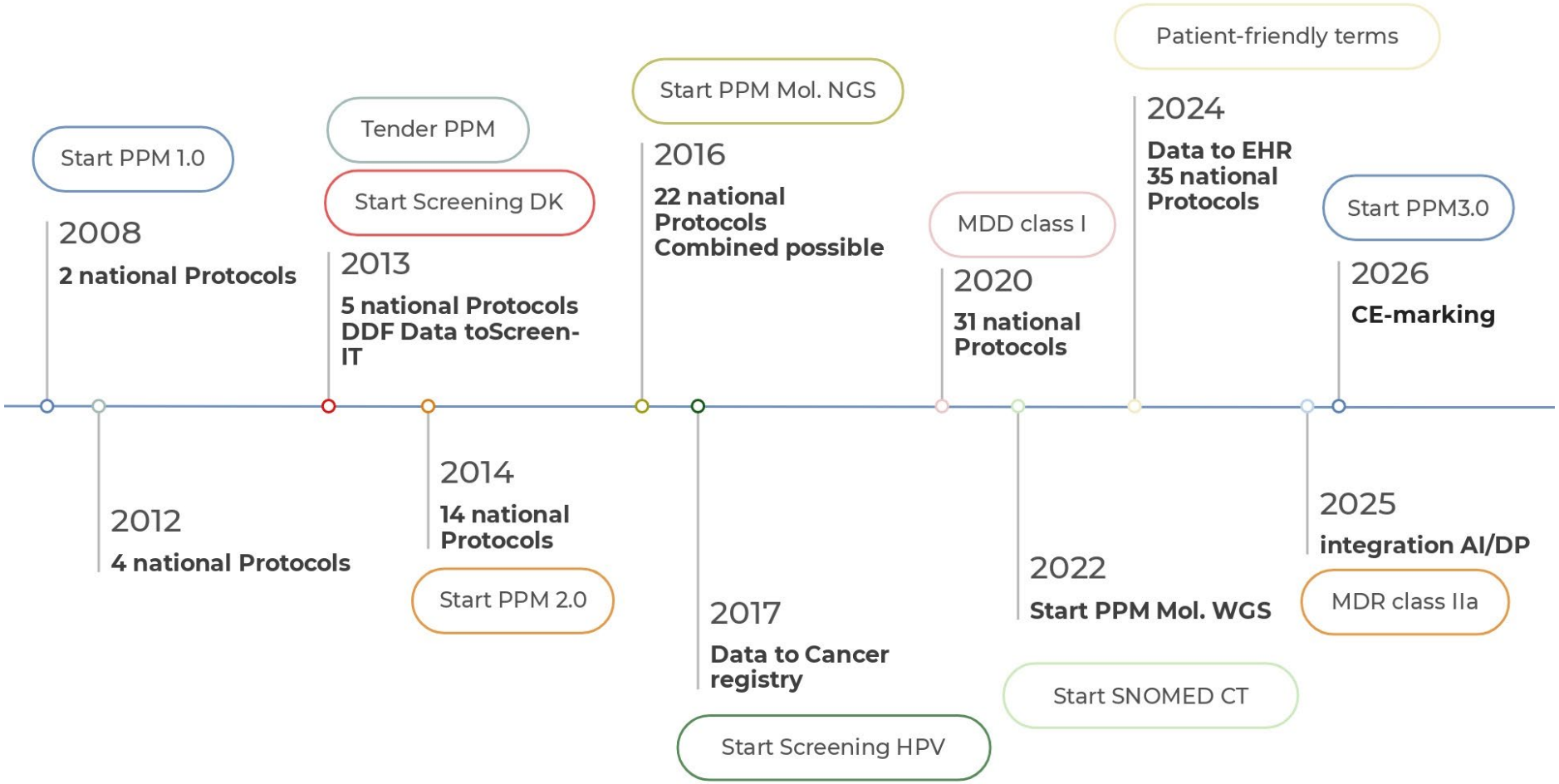
Level 6 of pathology reporting Molecular Diagnostics (Palga, Netherlands)

The layers of interoperability



Timeline implementation & development of SSR (Palga, Netherlands)



Timeline uptake of SSR (Palga, Netherlands)

Timeline implementation & development of SSR

Landmarks:

2009 Start Breast & ColoRectal Protocols

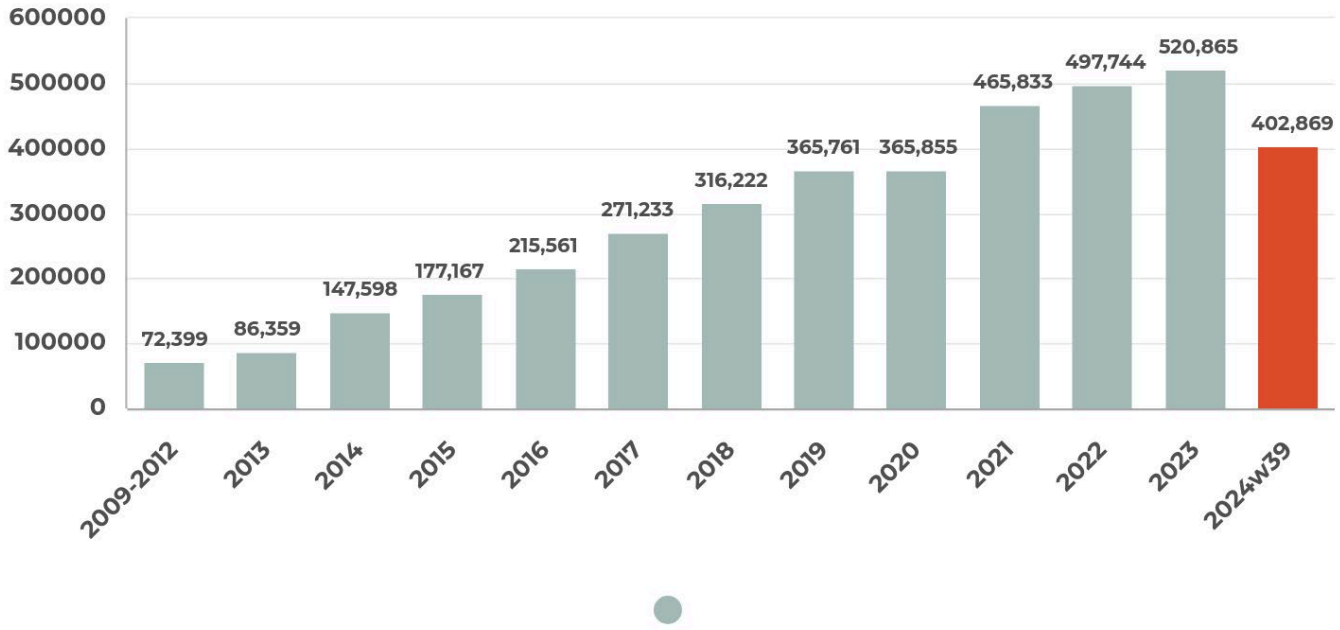
2013 Start Population Screening on Bowel cancer

2013 Introduction current PPM

2014 Release of first 3 National Protocols for current PPM

2020 Influence Covid-19

Number of Standardized Structured Reports (SSR) annually included in the national database Palga 2009-2024w39 (N=3.905.466 cumulative) CRIS3/4 excluded



Implementation of SSR (Palga, Netherlands)

Timeline implementation & development of SSR

Virchows Archiv
https://doi.org/10.1007/s00428-019-02609-6

ORIGINAL ARTICLE

Check for updates

Identification of barriers and facilitators in nationwide implementation of standardized structured reporting in pathology: a mixed method study

J. E. M. Swillens[1] · C. E. Sluijter[2,3] · L. I. H. Overbeek[2] · I. D. Nagtegaal[2,3] · R. P. M. G. Hermens[1]

Received: 22 March 2019 / Revised: 5 June 2019 / Accepted: 16 June 2019

Table 2: Barriers and facilitators related to implementation of SSR according to pathologists (focus group interview: qualitative study)

Domain	Barriers	Facilitators
SSR	- Conclusion is same as microscopy, no added value anymore - Pathologists argue that there is no room for nuance in the SSR* - Use of SSR is not always useful/easy - The format of the SSR-module is too strict - Following the Dutch guidelines could lead to out of date reports - The SSR-module is not user friendly - Use is not compatible with current practice	- It is clear why the SSR was implemented - The PALGA protocol modules ensures a uniform pathology report - Implementation of the SSR modules leads to discussion of definitions, more uniformity among pathologists
Professional (pathologist)	- The uncertainty of the pathologists opinion disappears, which is undesirable for the clinicians *	- Pathologists feel that PALGA listens to them for input in the SSR-modules by the PALGA working group.
Social setting	- Communication among pathologists and within the multidisciplinary team does not increase due to more black and white conclusions and less explanation of conclusions*	- Clinicians prefer SSR
Organizational factors	- SSR is not compatible with other hospital systems	
Incentives/resources and (inter)national guidelines		- SSR helps to collect structured data for multiple registration databases, such as the Netherlands Cancer Registry and the Dutch Institute for Clinical Auditing

* Barriers which were also mentioned as a facilitator are only shown in the barriers column

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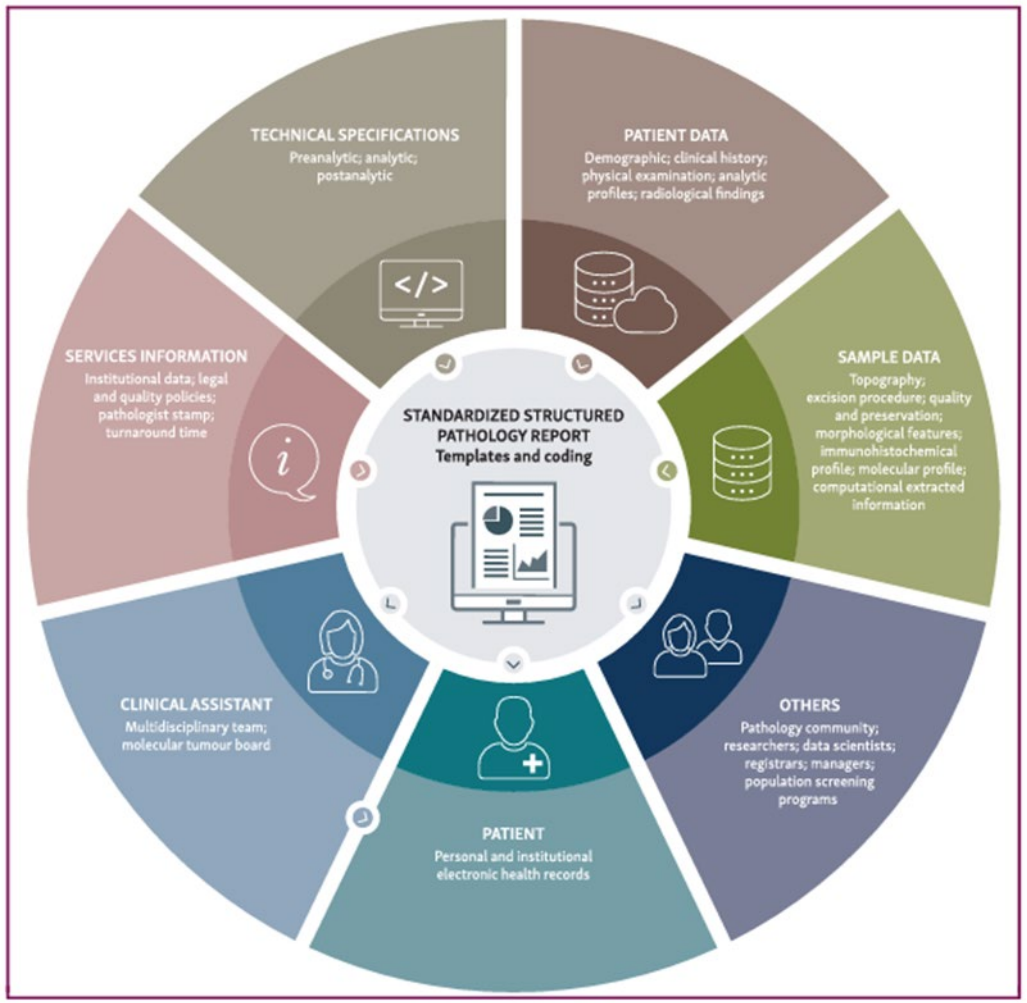
Summarizing "Standardized Structured Reporting"

Timeline implementation & development of SSR



ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ESMO REAL WORLD DATA AND DIGITAL ONCOLOGY

PERSPECTIVES

The 1 million words pathology report or the challenge of a reproducible and meaningful message

C. Eloy[1,2*], P. Seegers[3], E. Bazyleva[4] & F. Fraggetta[5]

[1]Pathology Laboratory, Institute of Molecular Pathology and Immunology of University of Porto (IPATIMUP), Porto; [2]Pathology Department, Medical Faculty of University of Porto, Porto, Portugal; [3]Palga, National Pathology Databank, Houten, the Netherlands; [4]Belgian Society of Pathology, Brussels, Belgium; [5]Pathology Department, Gravina Hospital, Caltagirone, ASP Catania, Italy

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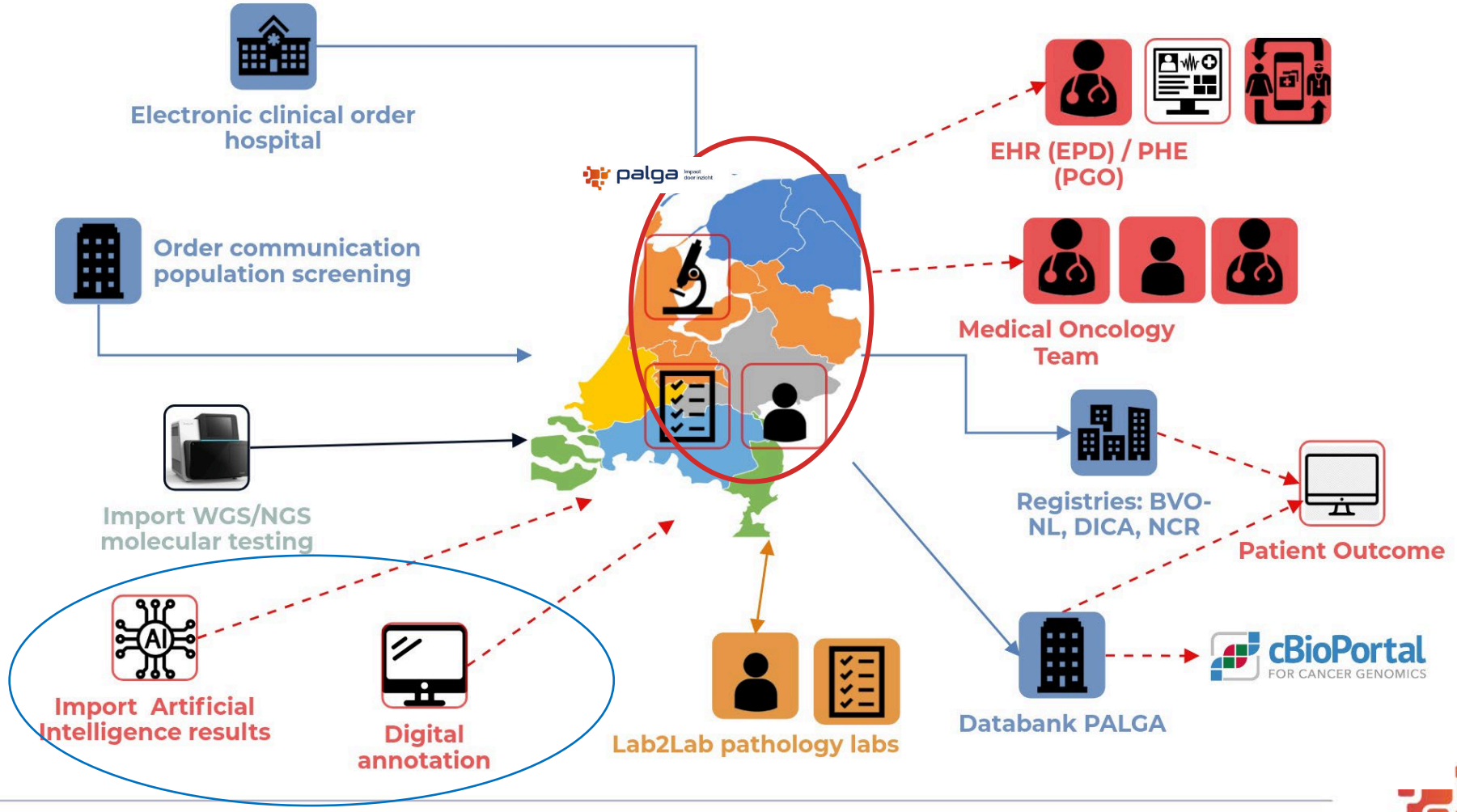
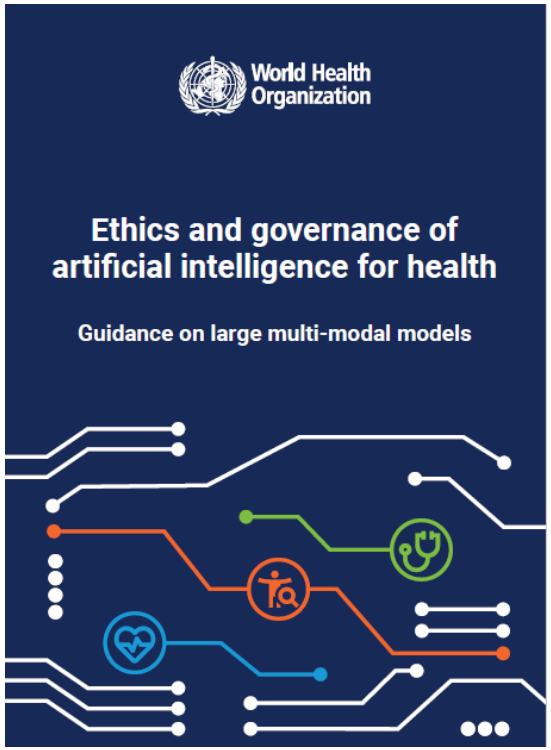
Process flow SSR in the healthcare chain, Netherlands

Timeline implementation & development of SSR



Artificial intelligence in healthcare (in medical reports)

Future perspectives



The principles should guide the development and deployment of AI in healthcare by a wide range of stakeholders, including governments, public sector agencies, researchers, companies and implementers.

The principles are: (1) protect autonomy; (2) promote human Well-being, human safety, and the public interest; (3) ensure transparency, "explainability," and intelligibility; (4) foster responsibility and accountability; (5) ensure inclusiveness and equity; and (6) promote AI that is responsive and sustainable

Table 1. Potential benefits and risks in various uses of LMMs in health care

Use	Potential or proposed benefits	Potential risks
Diagnosis and clinical care	Assist in managing complex cases and review of routine diagnoses Reduce the communication workload of health-care providers ("keyboard liberation") Provide novel insights and reports from various unstructured forms of health data	Inaccurate, incomplete or false responses Poor quality training data Bias (of training data and responses) Automation bias Degradation of skills (of health-care professionals) Informed consent (of patients)

Artificial intelligence and SSR, revolutionizing diagnostic accuracy
Future perspectives

Standardization SR/SSR:

- Minimal datasets ICCR templates
- On the European level, aline SNOMED CT terminology bindings

Implementing Molecular diagnostics:

- Create standardization on mutations

HDAB and EHDS:

- European data catalogue for MDR CE-IVD
- European standardization on quality label
- European standardization on meta-data

Name and Version of the AI Software:

- AI model used (e.g., “XYZ AI Algorithm Version 2.1”, CE- number, EUDAMED number)

Purpose/Function of the AI Model:

- Intended use (e.g., cancer diagnosis, tumor classification)
- Explainability (as discussed in Florence)

Model Performance Metrics:

- Model performance metrics:
  - **Accuracy**: Percentage of correct predictions.
  - **Sensitivity**: Model's ability to correctly identify positive cases.
  - **Specificity**: Ability to correctly identify negative cases.
- *notable performance benchmarks in research or clinical trials.*

Type of Images Analyzed:

- Types of images processed by the AI (e.g., whole slide images, regions of interest).
- Detail the medical context (e.g., histopathological slides, microscopy images).

Image Acquisition Parameters:

- Acquisition process:
  - **Scanner model**: Name the scanner used (e.g., Leica Aperio, Philips IntelliSite).
  - **Magnification**: Highlight magnification levels used (e.g., 20x, 40x).

Tumor Type/Subtype Predictions:

- Predicts types and subtypes (e.g., adenocarcinoma, squamous cell carcinoma)

Grade/Stage Predictions:

- AI determines tumor grade and stage based on image analysis.

Risk Stratification Scores:

- Provides stratification into low, intermediate, or high-risk groups.

Known Limitations:

- Limited by image quality, rare tumor types, and sensitivity to artifacts.

Artifacts/Quality Issues:

- Poor-quality images (e.g., blur, stain variations) may affect AI performance.

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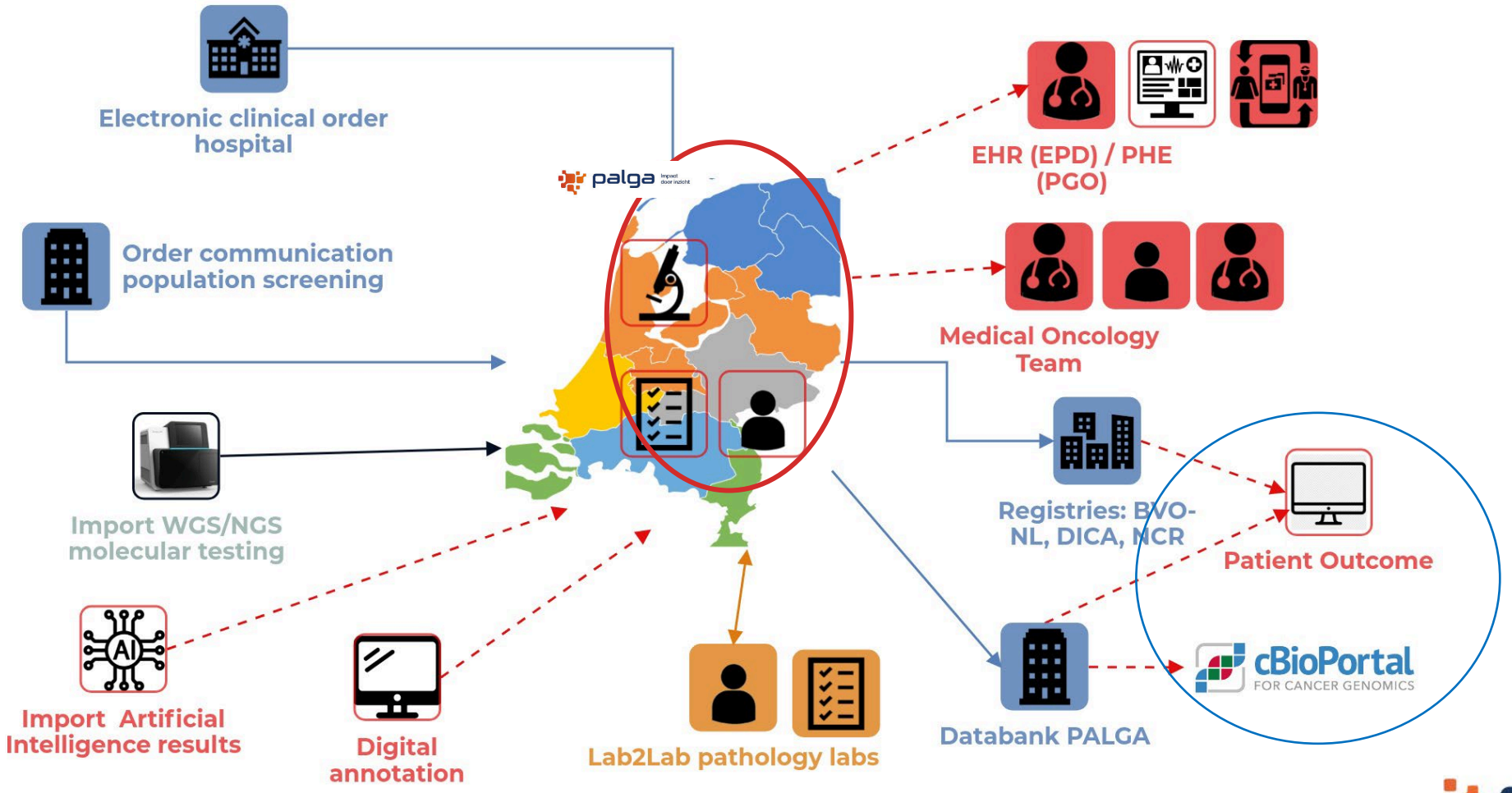
Process flow SSR in the healthcare chain, Netherlands

Timeline implementation & development of SSR



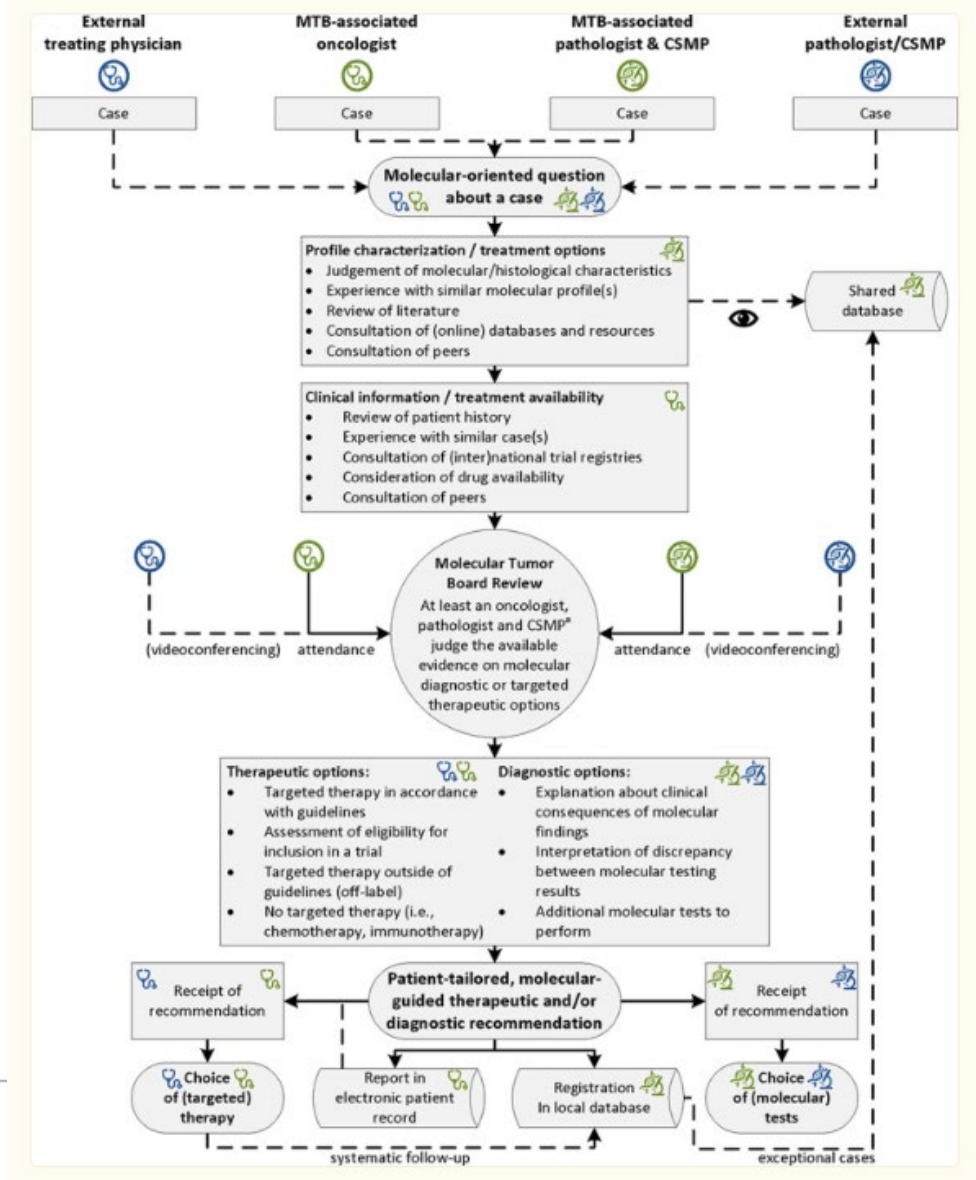
MOT/MTB with molecular diagnostics & patient outcome, *cBioPortal*

Future perspectives

Oncologist. 2021 Aug; 26(8): e1347–e1358.
Published online 2020 Nov 10. doi: 10.1002/onco.13580
PMCID: PMC8342588
PMID: 33111480

Multicenter Comparison of Molecular Tumor Boards in The Netherlands: Definition, Composition, Methods, and Targeted Therapy Recommendations

Bart Koopman, [1] Harry J.M. Groen, [2] Marjolijn J.L. Ligtenberg, [3,4] Katrien Grünberg, [3] Kim Monkhorst, [7] Adrianus J. de Langen, [8] Mirjam C. Boelens, [7] Marthe S. Paats, [9] Jan H. von der Thüsen, [10] Winand N.M. Dinjens, [10] Nienke Solleveld, [11] Tom van Wezel, [7,11] Hans Gelderblom, [12] Lizza E. Hendriks, [13] Ernst-Jan M. Speel, [14] Tom E. Theunissen, [14] Leonie I. Kroeze, [3] Niven Mehra, [5] Berber Piet, [6] Anthonie J. van der Wekken, [2] Arja ter Elst, [1] Wim Timens, [1] Stefan M. Willems, [1,15] Ruud W.J. Meijers, [15] Wendy W.J. de Leng, [15] Anne S.R. van Lindert, [16] Teodora Radonic, [17] Sayed M.S. Hashemi, [18] Daniëlle A.M. Heideman, [17] Ed Schuuring, [1] and Léon C. van Kempen [1]



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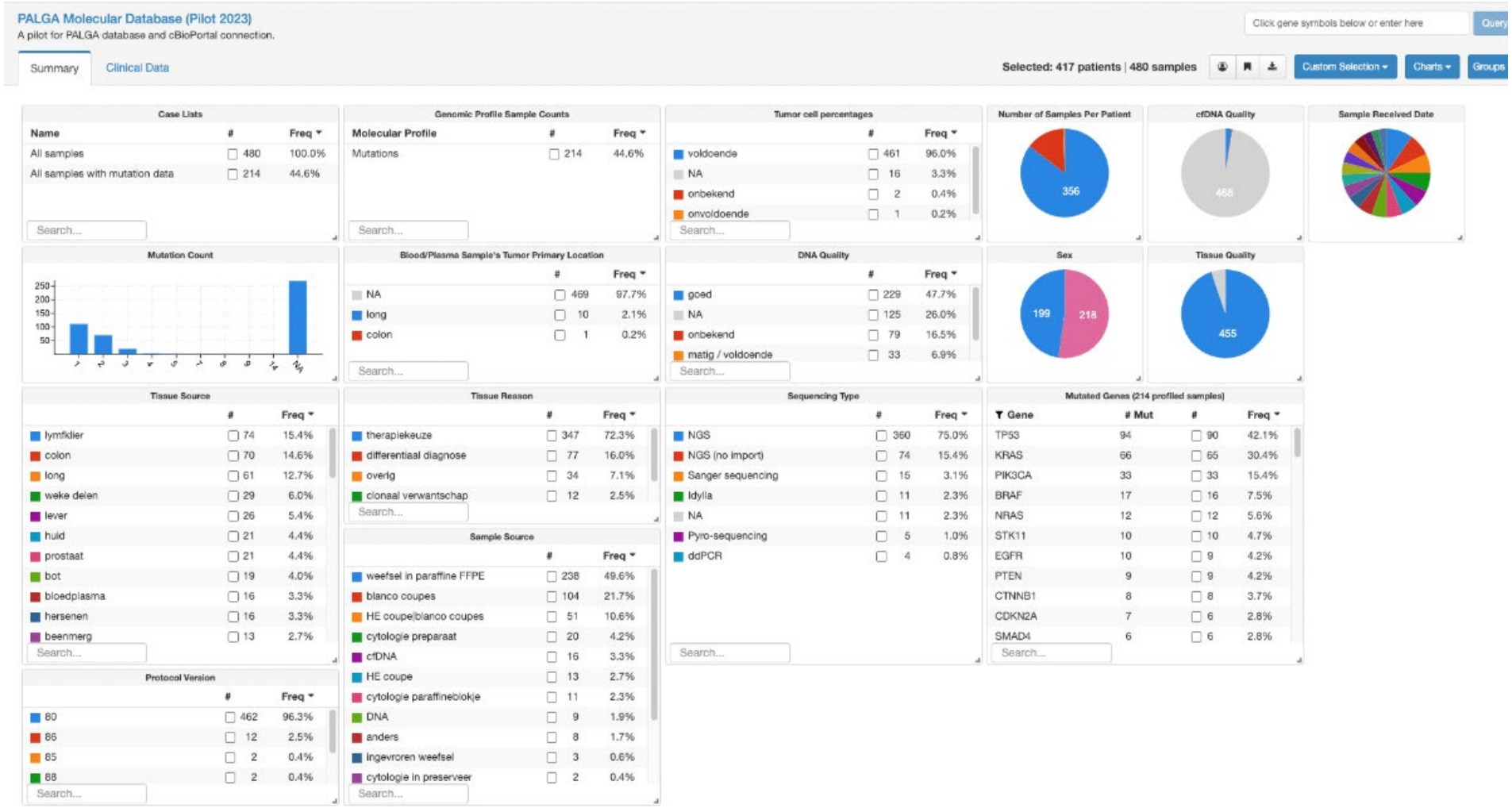
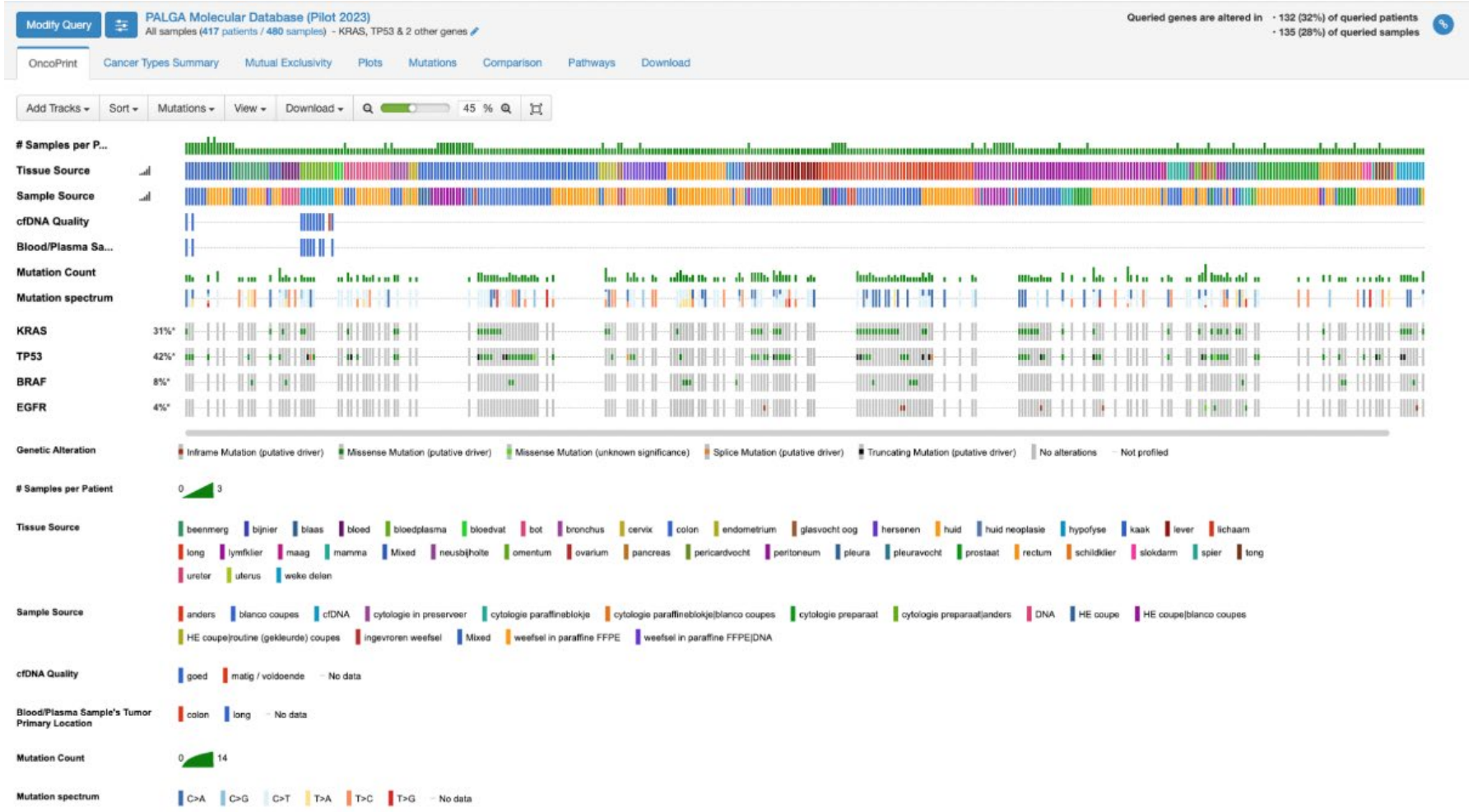
MOT/MTB with molecular diagnostics & patient outcome, *cBioPortal*

Future perspectives



MOT/MTB with molecular diagnostics & patient outcome, *cBioPortal*

Future perspectives



MOT/MTB with molecular diagnostics & patient outcome

Future perspectives

› Cancers (Basel). 2021 Jul 20;13(14):3641. doi: 10.3390/cancers13143641.

A Nationwide Study on the Impact of Routine Testing for *EGFR* Mutations in Advanced NSCLC Reveals Distinct Survival Patterns Based on *EGFR* Mutation Subclasses

Bart Koopman [1], Betzabel N Cajiao Garcia [1], Chantal C H J Kuijpers [2], Ronald A M Damhuis [3], Anthonie J van der Wekken [4], Harry J M Groen [4], Ed Schuuring [1], Stefan M Willems [1], Léon C van Kempen [1]

Affiliations + expand

PMID: 34298851 PMCID: PMC8307492 DOI: 10.3390/cancers13143641

› Diagnostics (Basel). 2022 Mar 9;12(3):668. doi: 10.3390/diagnostics12030668.

Detection of *NTRK* Fusions and TRK Expression and Performance of pan-TRK Immunohistochemistry in Routine Diagnostics: Results from a Nationwide Community-Based Cohort

Bart Koopman [1], Chantal C H J Kuijpers [2], Harry J M Groen [3], Wim Timens [1], Ed Schuuring [1], Stefan M Willems [1], Léon C van Kempen [1]

Affiliations + expand

PMID: 35328221 PMCID: PMC8946871 DOI: 10.3390/diagnostics12030668

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MOT/MTB with molecular diagnostics & patient outcome

Future perspectives

Zorginstituut Nederland

Zorginzicht > Kwaliteitsinstrumenten >

Kwaliteitsstandaard Organisatie van moleculaire pathologie diagnostiek in de oncologie

Kwaliteitsstandaard | Kanker

Moleculaire diagnostiek is een verzamelnaam voor voorspellende testen die genetische eigenschappen van tumoren bepalen. Die zijn belangrijk voor het stellen van de diagnose, de prognose en het voorspellen van de gevoeligheid voor bepaalde geneesmiddelen tegen uitgezaaide kanker. De kwaliteitsstandaard beschrijft de organisatie van moleculaire patholo-gie diagnostiek in de oncologie.

Status	Opgenomen in het Register
Opgenomen in het Register	28 november 2023
Herzieningsdatum	1 december 2025

Quality Standards, in the Netherlands

Organization of molecular pathology diagnostics in oncology

NVALT
KNL integraal kankercentrum Nederland
nvmo
palga
nvog
Zorginstituut Nederland
NEDERLANDSE VERENIGING VOOR PATHOLOGIE
PRAKTIJKMONITOR MOLECULAIRE DIAGNOSTIEK

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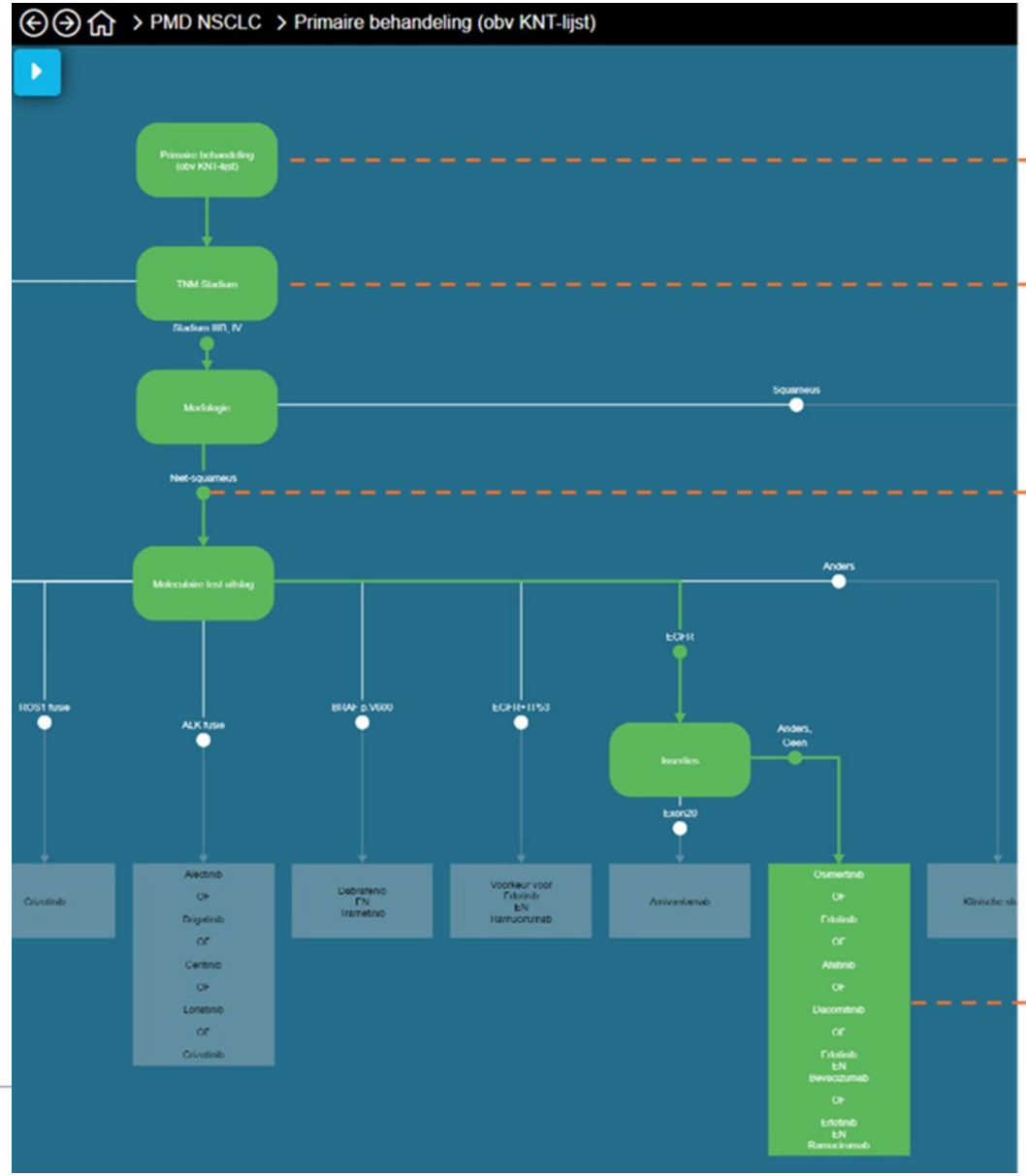
MOT/MTB with molecular diagnostics & patient outcome

Future perspectives

This is a screenshot of the Oncoguide application showing a decision algorithm for choosing a primary treatment for patients with stage IV non-small cell lung cancer based on the Clinical Necessary Target list



Start care path

TNM stage (UICC)

Morphology

recommendations

MOT/MTB with molecular diagnostics & patient outcome

Future perspectives

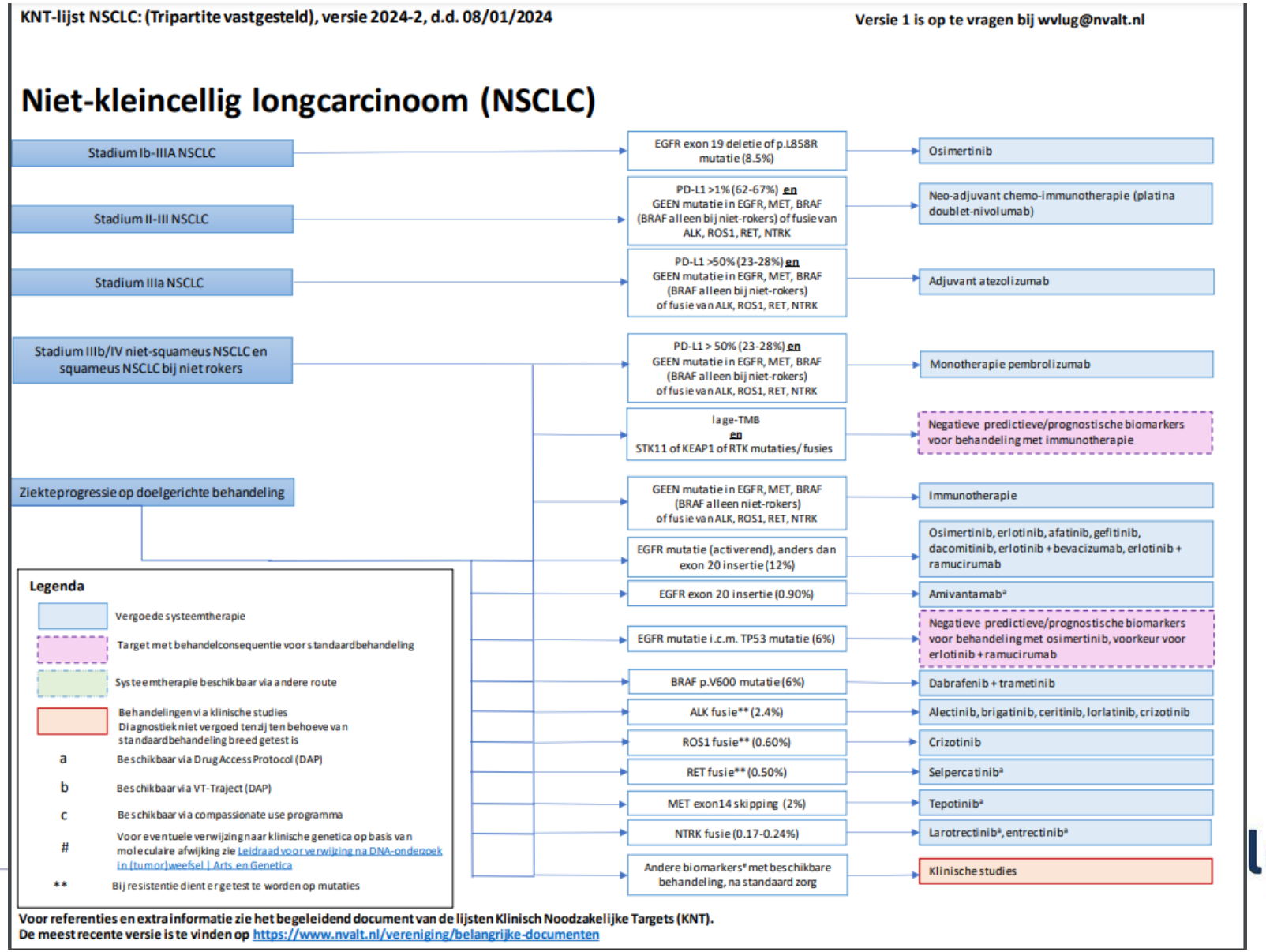
Clinical Necessary Target Lists

> Cervix carcinoma
> Cholangial carcinoma
> Colorectal carcinoma
> Endometrium carcinoma
> GIST
> HNSCC
> Gastric carcinoma
> Breast cancer
> Melanoma
> Renal cell carcinoma
> NSCLC

KNT List NSCLC v2 2024-01-08

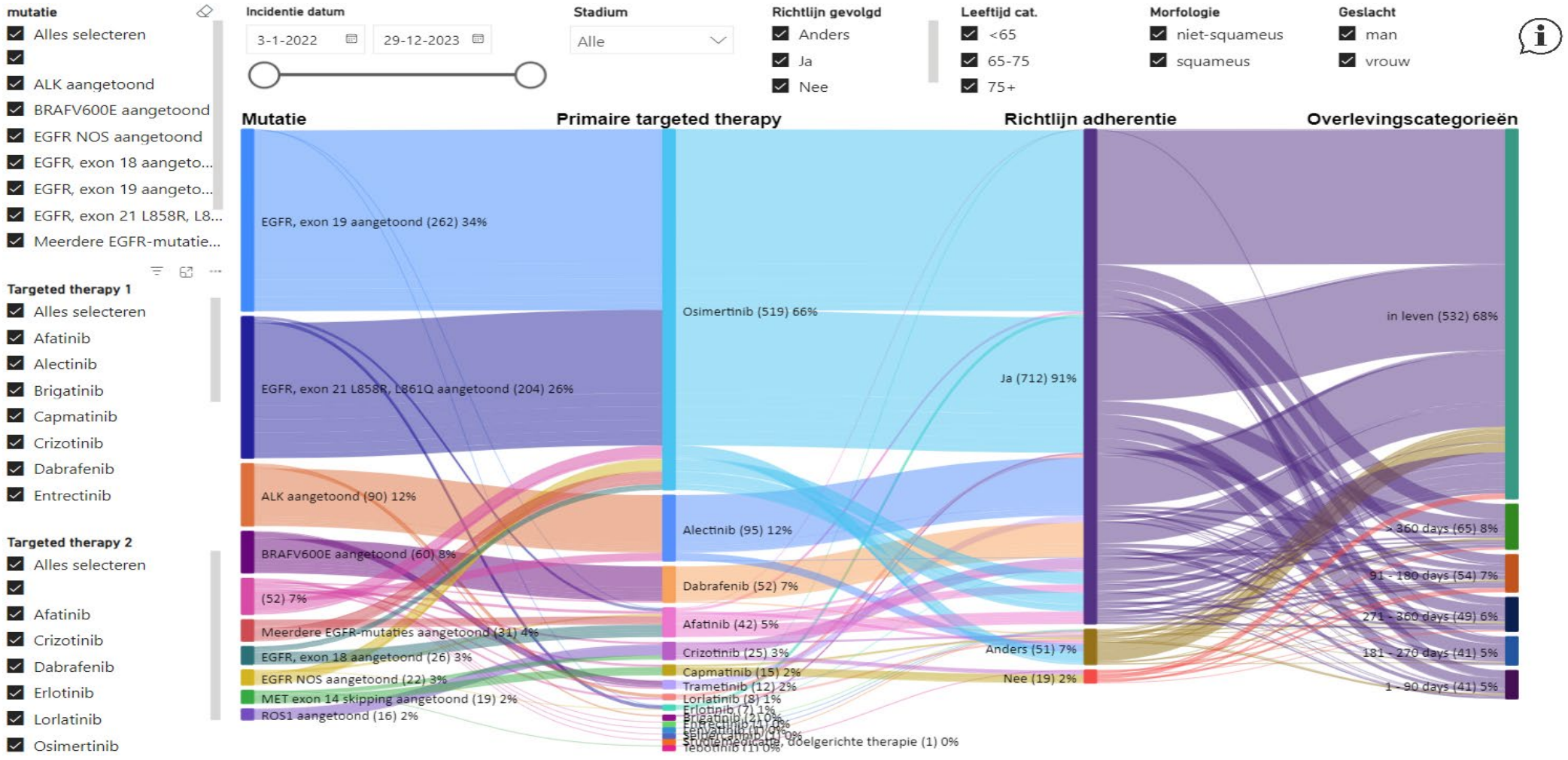
Version 1 can be requested from wvlug@nvalt.nl

> Esophageal carcinoma
> Ovarian carcinoma
> Pancreas carcinoma
> Prostate carcinoma
> Thyroid carcinoma
>Salivary gland carcinoma
> Urothelial Cell Carcinoma



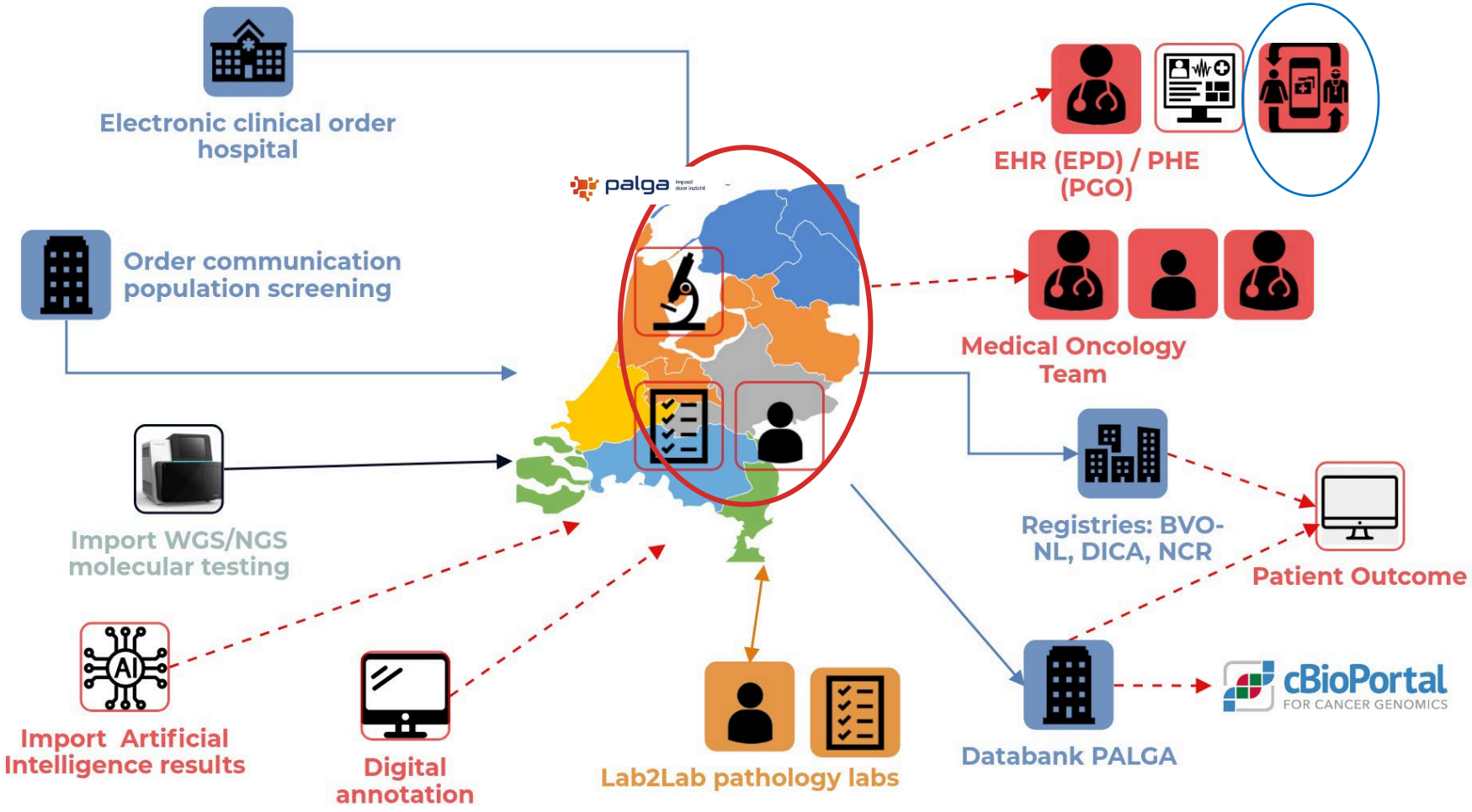
MOT/MTB with molecular diagnostics & patient outcome

Future perspectives



Process flow SSR in the healthcare chain, Netherlands

Timeline implementation & development of SSR



Pilot study patient-friendly terms

Why needed
Personal Health Environment (PHE)

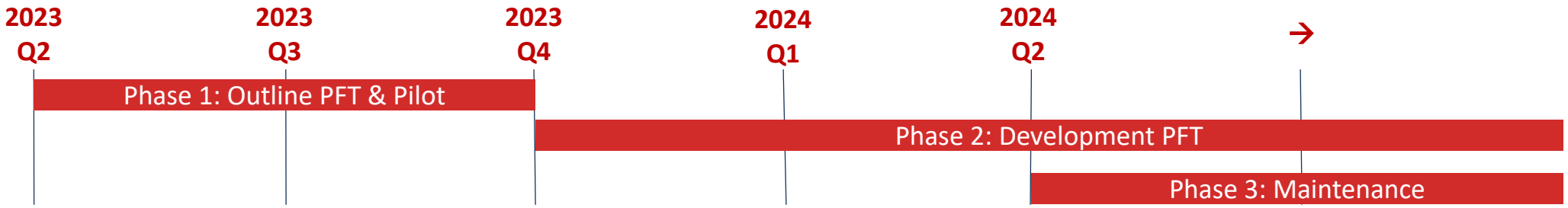
- Patients have more access to their data (EHDS)
- Patients are getting more control over their data
  - *What to share or not*
- The Netherlands has more than 1,2 million low-literate people
- Plain text with cancer in the report has an impact on a patient

- Nictiz is setting up a project to make the content of a medical report more understandable for patients

- Nictiz is adding patient-friendly terms and descriptions to the medical concepts in SNOMED International

- In the Pilot, we will combine Palga national protocol ColonBiopsy-TEM with patient-friendly terms and descriptions

Pilot study patient-friendly terms
Personal Health Environment (PHE)



Nictiz

palga

Pilot study patient-friendly terms

Personal Health Environment (PHE)

3

Medical translation organization and ChatGPT: creating new descriptions for 200 medical concepts

SCTID	Medical preferred term	Patiënt term	Rating term	Explanation of term	Descriptions	Rating description	Explanation assessment
1187332001 (morphologic abnormality)	adenocarcinoma	Klierkanker	Otherwise, namely ...	A form of cancer	This is a type of cancer that starts in the glands, the parts of your body that make mucus, such as in your lungs, intestines or breasts. This is the most common type of cancer. It usually grows very slowly. If someone has adenocarcinoma, it is important to act quickly because it can spread to other parts of the body.	**Otherwise, namely ...**	This is a type of cancer. It begins in cells that form glands. These glands make mucus, digestive juices and other fluids in different parts of your body such as lungs, chest, intestines, stomach, pancreas and prostate. Not all growths in these glands are adenocarcinoma, only the malignant ones are so called.
408645001	adenocarcinoma of colon	Colon cancer	Sufficient with minimal changes, namely ...	Certain type of colon cancer	This is a type of cancer that starts in the cells that make and release mucus in your colon. This is the most common form of colon cancer. This disease causes a malignant tumor to grow in the wall of the large intestine. This can cause problems when digesting food and the stool of waste products.	**Correct / sufficient**	
408645001	adenocarcinoma of colon		Otherwise, namely ...	Certain type of colon cancer	This is a type of cancer in the colon. The cancer develops in the glandular cells. These are the cells that make mucus, bodily fluids and hormones.	**Otherwise, namely ...**	This is a type of cancer that starts in the cells that make and release mucus in your colon. This is the most common form of colon cancer. This disease causes a malignant tumor to grow in the wall of the large intestine. This can cause problems when digesting food and the stool of waste products.
41329004	polyp	Tumour	Sufficient with minimal changes, namely ...	Polyp	This is a small, usually non-malignant growth of tissue. They can occur in multiple places in your body, but they are most common in the nose, intestines or uterus. A polyp can be in the form of a nodule, bump or peduncle. It can sometimes cause problems depending on the size and location.	**Sufficient with minimal changes, namely ...**	This is a small, usually benign tumor (polyp). They can occur in multiple places in your body but are most common in the nose, intestines, or uterus. A polyp can be in the form of a nodule, bump, or peduncle. It can sometimes cause problems depending on the size and location.
443961001 (disorder)	adenocarcinoma	Klierkanker	Sufficient with minimal changes, namely ...	A form of cancer	This is a type of cancer. It starts in cells that make glands. These glands make mucus, digestive juices and other fluids in different parts of your body such as lungs, chest, intestines, stomach, pancreas and prostate. Not all growths in these glands are adenocarcinoma, only the malignant ones are so called.	**Sufficient with minimal changes, namely ...**	This is a type of cancer. It begins in cells that form glands. These glands make mucus, digestive juices and other fluids in different parts of your body such as lungs, chest, intestines, stomach, pancreas and prostate. Not all growths in these glands are adenocarcinoma, only the malignant ones are so called.
443961001 (disorder)	adenocarcinoma	klierkanker	Sufficient with minimal changes, namely ...	A form of cancer	This is a type of cancer. The tumor arises in the glandular cells. These are the cells in the body that make mucus, bodily fluids and hormones.	**Otherwise, namely ...**	This is a type of cancer. It begins in cells that form glands. These glands make mucus, digestive juices and other fluids in different parts of your body such as lungs, chest, intestines, stomach, pancreas and prostate. Not all growths in these glands are adenocarcinoma, only the malignant ones are so called.
41329004	polyp		Otherwise, namely ...	Polyp	A polyp is a tumor on the mucous membrane. Polyps are mainly found in the intestines. They can be large or small. They are usually not dangerous.	**Otherwise, namely ...**	This is a small benign tumor (polyp). They can occur in multiple places in your body, but they are most common in the nose, intestines or uterus. A polyp can be in the form of a nodule, bump or peduncle. It can sometimes cause problems depending on the size and location.

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Pilot study patient-friendly terms

Personal Health Environment (PHE)

7

2300 patients are reviewing the descriptions on comprehension

Patients were asked to rate the **mixed assessment** on a scale of 1 to 4.

Mixed assessment of AI by level of education	
Primary education	3,45
Secondary education	3,68
Secondair vocational education	3,70
Higher vocational education	3,67
University	3,62
Translation Agency mixed assessment by level of education	
Primary education	3,44
Secondary education	3,66
Secondair vocational education	3,65
Higher vocational education	3,66
University	3,62

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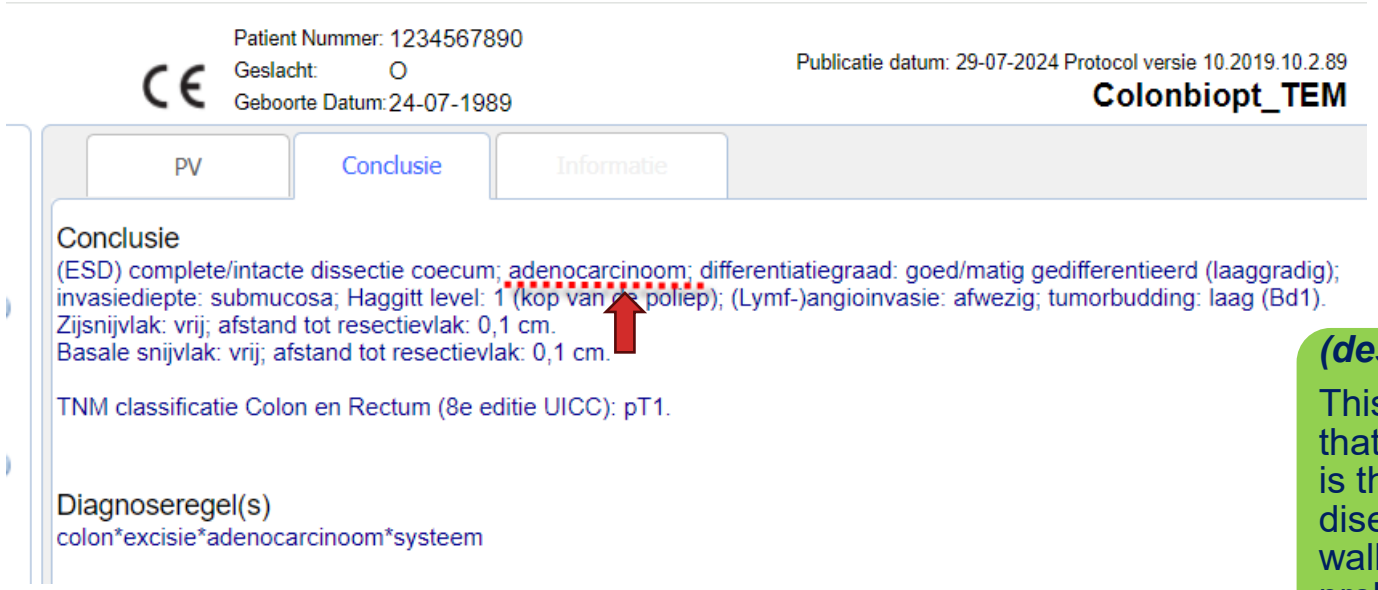
Pilot study patient-friendly terms

Personal Health Environment (PHE)



Patient Nummer: 1234567890
Geslacht: O
Geboorte Datum: 24-07-1989

Publicatie datum: 29-07-2024 Protocol versie 10.2019.10.2.89
Colonbiopt_TEM

PV | Conclusie | Informatie

Conclusie
(ESD) complete/intacte dissectie coecum; adenocarcinoom; differentiatiegraad: goed/matig gedifferentieerd (laaggradig); invasiediepte: submucosa; Haggitt level: 1 (kop van de poliep); (Lymf-)angioinvasie: afwezig; tumorbudding: laag (Bd1).
Zijsnijvlak: vrij; afstand tot resectievlak: 0,1 cm.
Basale snijvlak: vrij; afstand tot resectievlak: 0,1 cm.

TNM classificatie Colon en Rectum (8e editie UICC): pT1.

Diagnoseregel(s)
colon*excisie*adenocarcinoom*systeem

SCTID 408645001 (*Patiënt term*)
Colon cancer

(*Explanation of the term*)
Certain type of colon cancer

(description)
This is a type of cancer that starts in the cells that make and release mucus in your colon. This is the most common form of colon cancer. This disease causes a malignant tumor to grow in the wall of the large intestine. This can cause problems when digesting food and the stool of waste products.

Foundation kanker.nl (*further information*)
https://www.kanker.nl/kankersoorten/darmkanker-dikkedarmkanker/algemeen/wat-is-darmkanker

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Take home messages

Standardized Structured Reporting (SSR) is becoming more and more important for primary and secondary use and must include:

Baseline

- *International minimal datasets (CAP, ICCR, RCPath, RCPA)*
- *Cancer staging TNM (AJCC, UICC)*
- *International coding systems (SNOMED-CT, LOINC, ICD-O)*
- *Standardization in data exchange (HL7-CDA, FHIR, openEHR)*

Challenging

- *Standardization on non-core elements (concensus articles, guidelines etc.)*
- *Standardization on functional diseases (concensus articles, guidelines etc.)*
- *Standardization on molecular diagnostics (ESP, EEIC, AMP, etc.)*
- *Standardization on artificial intelligence and digital annotations (DPA, ESDP, ASDP, JSDP, vendors, etc.)*
- *Quality labels and metadata (HDAB, EHDS) (EU only)*

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Thank you for your attention

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Infographics: Alexander Ahmedov, sashaahmedov@gmail.com

palga Impact door inzicht