Interoperability Standards and Their Impact on the Future of Cancer Diagnostics

W. Scott Campbell, PhD, MBA
Alex Goel, MI
Sandy Jones

OCTOBER 18 | 3–4 PM PT

COLLEGE of AMERICAN PATHOLOGISTS
Laboratory Quality Solutions

CAP24 | LAS VEGAS
#PATHDATA

Interoperability Standards and Their Impact on the Future of Cancer Diagnostics

Sandy Jones
Public Health Advisor (Informatics)
Cancer Surveillance Branch
Division of Cancer Prevention and Control

October 18th, 2024

Future of Cancer Data Summit: Harnessing the Power of Pathology Data

Disclosures

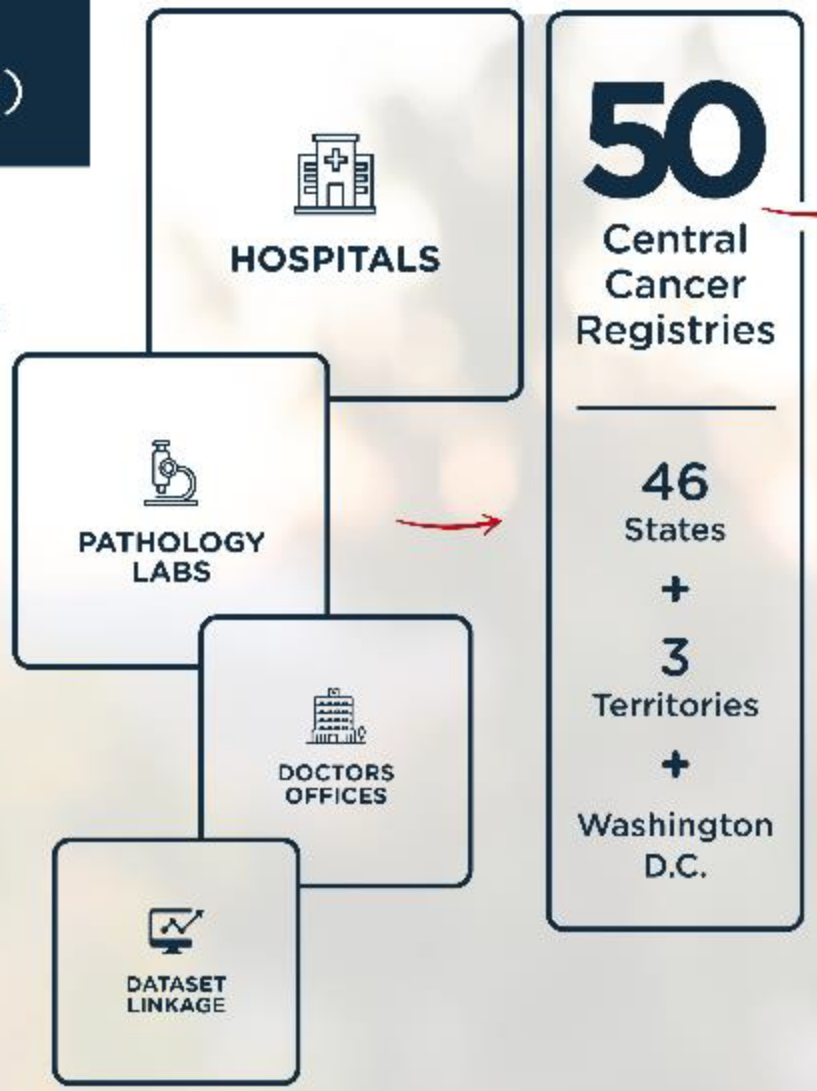
Nothing to disclose

The Question That Forever Changed Cancer Registration

Why are so many Vermont women dying of breast cancer?

National Program of Cancer Registries (NPCR)

- Coordinates collection, verification and reporting of important information on all reportable cancer cases.
- Helps identify better ways to prevent, treat and control cancer.



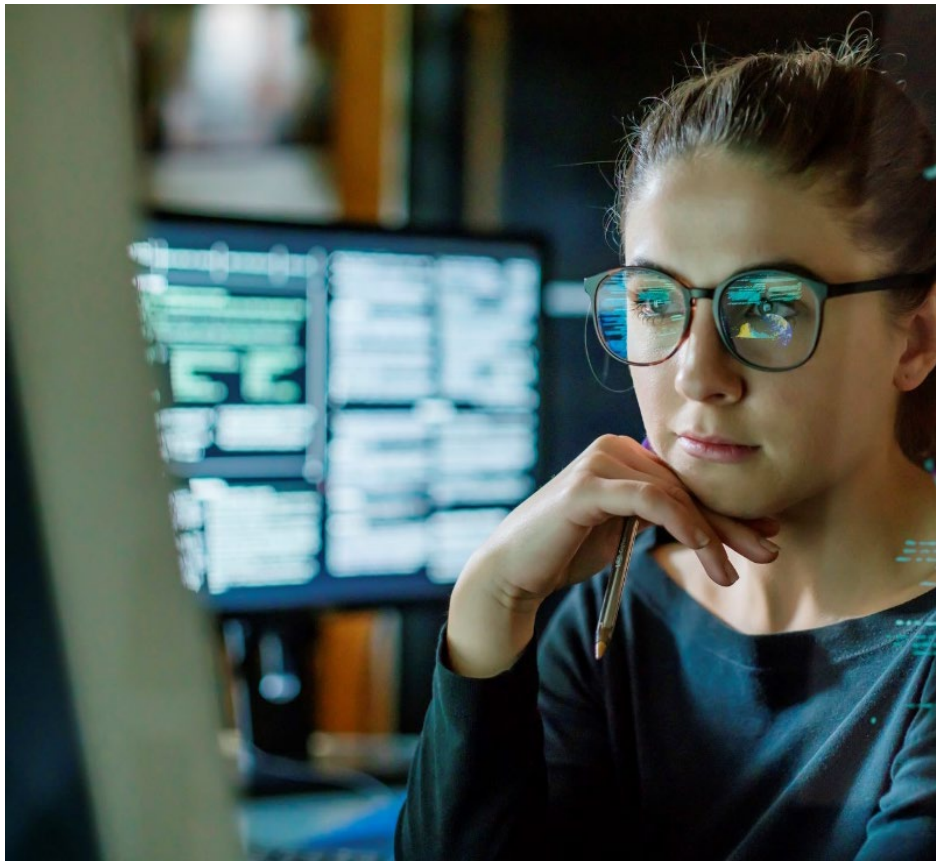
Over 1.7 million new cases & nearly 600,000 deaths annually.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Measuring Progress. Targeting Action.

Changing Data Needs

- Rapid case reporting
- Expansion of data collection to enable research and analysis of treatment modalities and other factors beyond incidence
  - Outcomes
  - Continuity of care
  - Genomic variations
  - Social determinants of health
- More responsive coordination with public health officials to define useful data analysis and reporting capabilities.



Use of Complete, High-Quality, and Timely EHRs to Enhance Patient Care and Public Health

1. Patient is diagnosed with a reportable condition, such as COVID-19
2. Healthcare provider enters patient's information into the electronic health record (EHR)
3. Data in the EHR automatically triggers a case report that is validated and sent to the appropriate public health agencies if it meets reportability criteria
4. The public health agency receives the case report in real time and a response about reportability is sent back to the provider
5. State or local health department reaches out to patient for contact tracing, services, or other public health action

Needs and Challenges

Hospitals

- Collection of data items not usually found in patient charts
- Treatment administered outside hospital difficult to capture
- Burden of manual reporting

Providers

- Competing priorities
- Staff time required to identify cases and treatments
- Lack of supporting information technologies

Laboratories

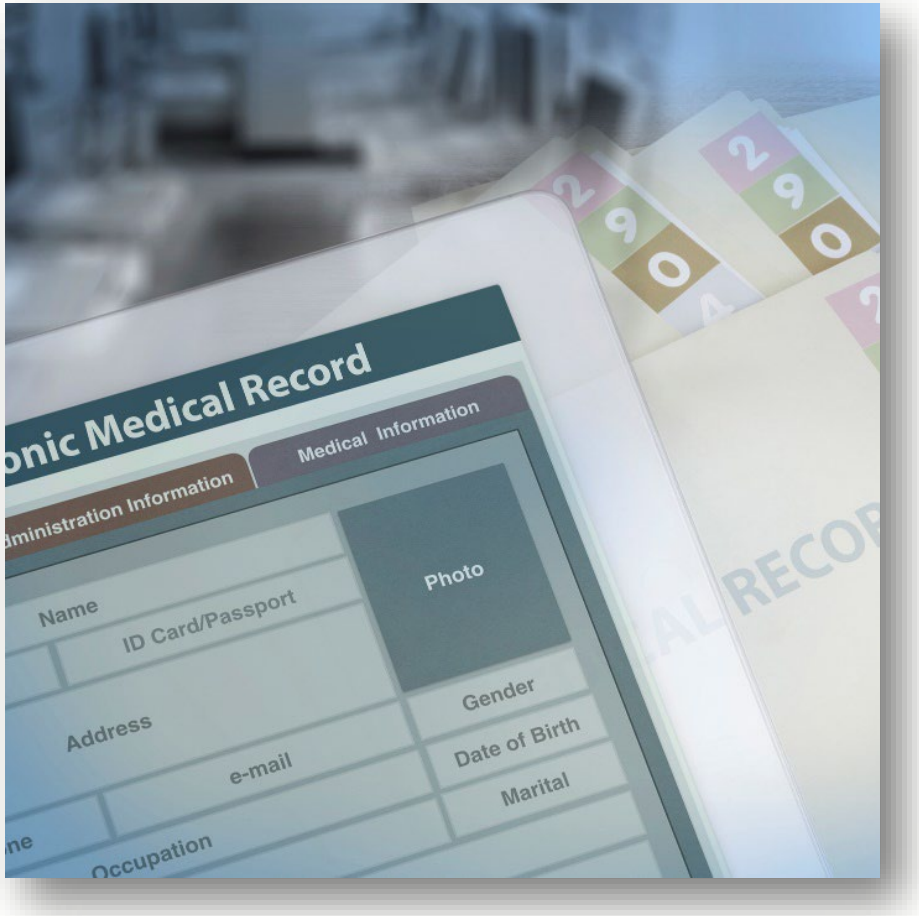
- Redundant coding and data recoding
- Burden of manual reporting
- Maintaining multiple transmission protocols

Central Registries

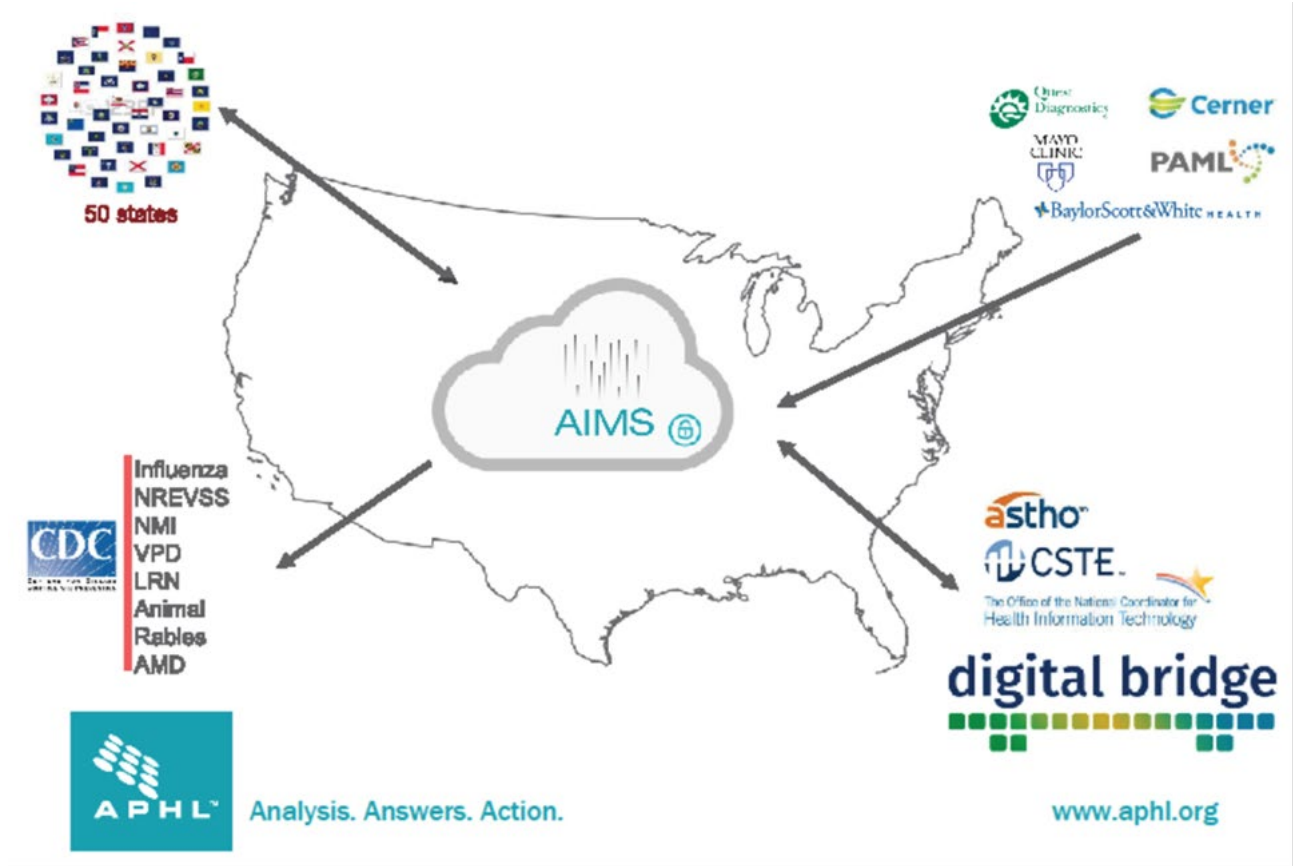
- State and local consent law differences
- Missing information
- Changing classifications and staging guidelines
- Staff time spent case finding and abstracting

Leveraging Electronic Health Record (EHR) Interoperability Initiatives for Improved Healthcare

- Use EHR data for multiple health domains and varied use cases
- Implementation guides and secure cloud architecture for cancer case reporting (HL7 FHIR and APHL AIMS)
- Certification of EHRs compliance with CMS Promoting Interoperability Program, United States Core Data for Interoperability (USCDI) and USCDI+ Cancer Early Incidence
- Minimum Common Oncology Data Elements (mCODE), Common Oncology Data Elements eXtensions (CodeX) HL7 FHIR Accelerator

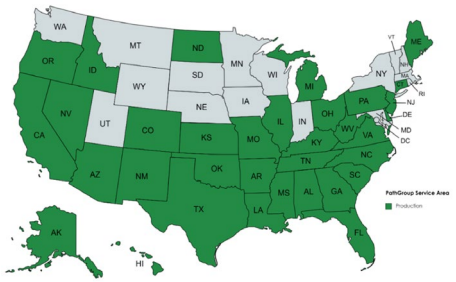


A National Resource for Interoperability: Association of Public Health Laboratories (APHL) Informatics Messaging Services (AIMS)

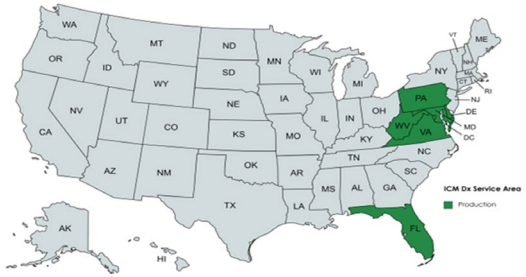


Cancer Pathology Reporting in Production using APHL AIMS

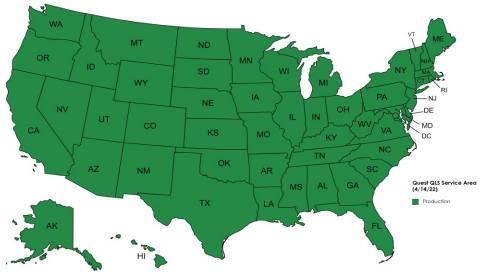
PathGroup Laboratories



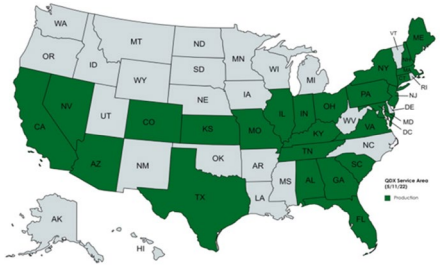
ICM Diagnostics



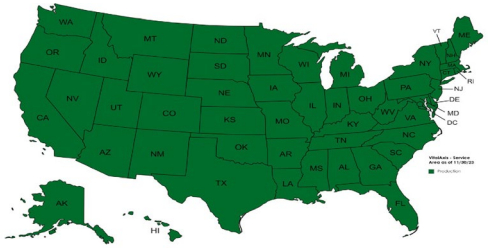
Quest Diagnostics



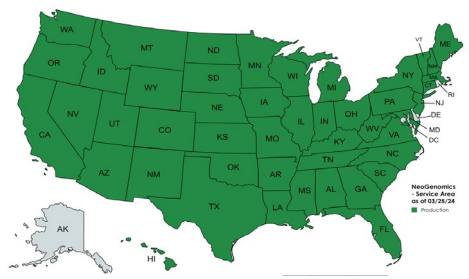
QDx Laboratories



Vital Axis Laboratory Information System



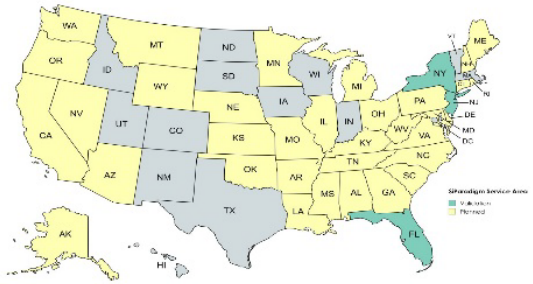
NeoGenomics



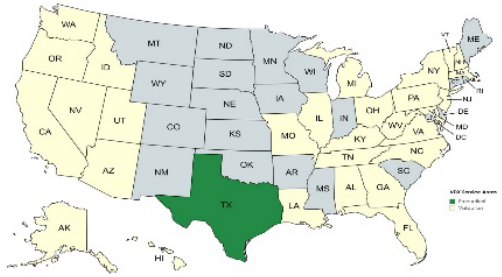
Inform Diagnostics

Laboratories Onboarding to Report Cancer Pathology using APHL AIMS

SiParadigm Labs



Vizia Diagnostics



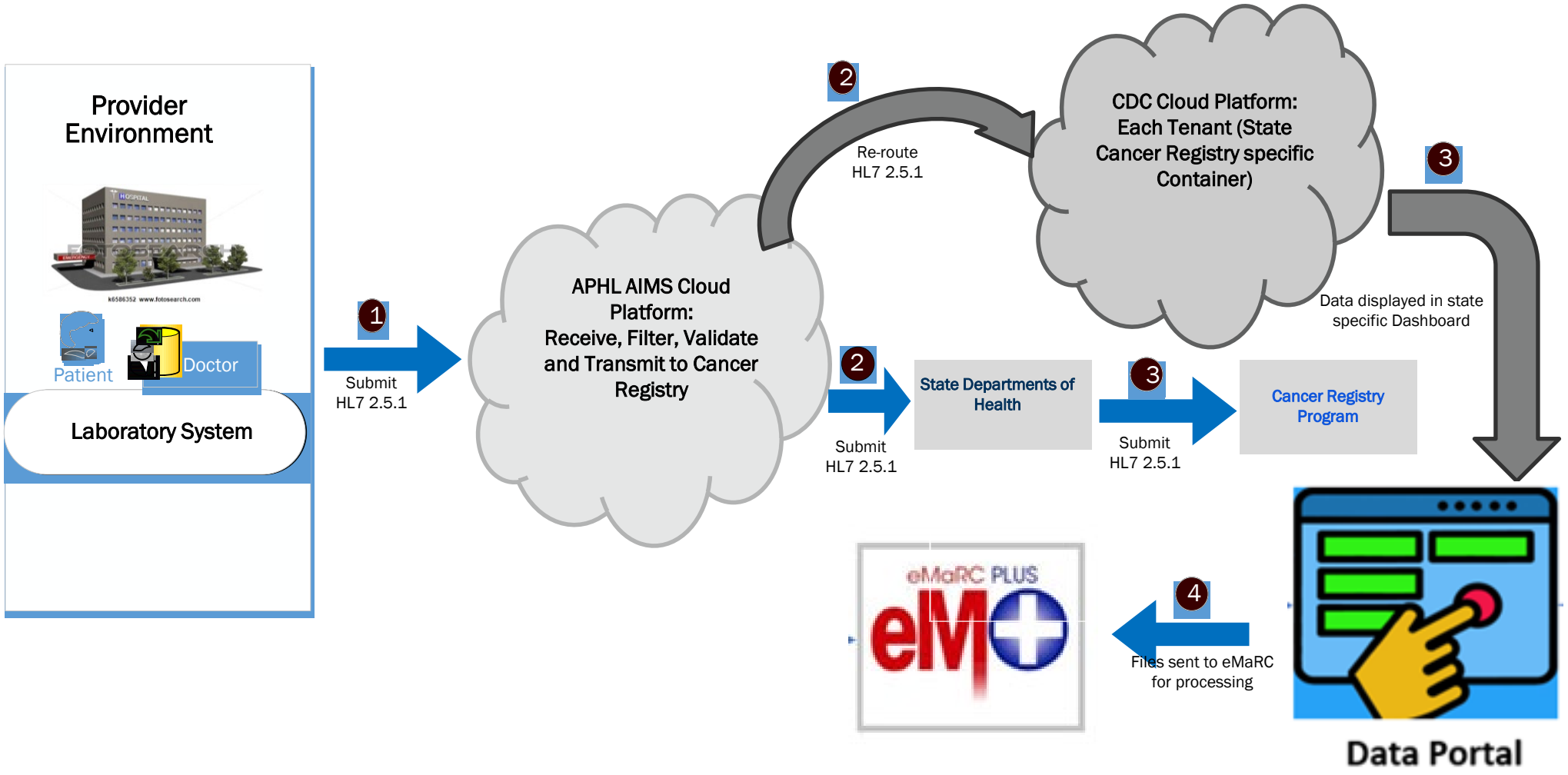
AP Derm Services

Laboratory Name	HL7 Message Developed
Mayo Medical Laboratories	In Progress
BioReference	In Progress
Sonic Healthcare (CBL Path, CPL Path, Aurora Dx, ProPath)	In Progress
Avero Dx	
Summit Health	

Vision for Cancer Surveillance Reporting in Five Years

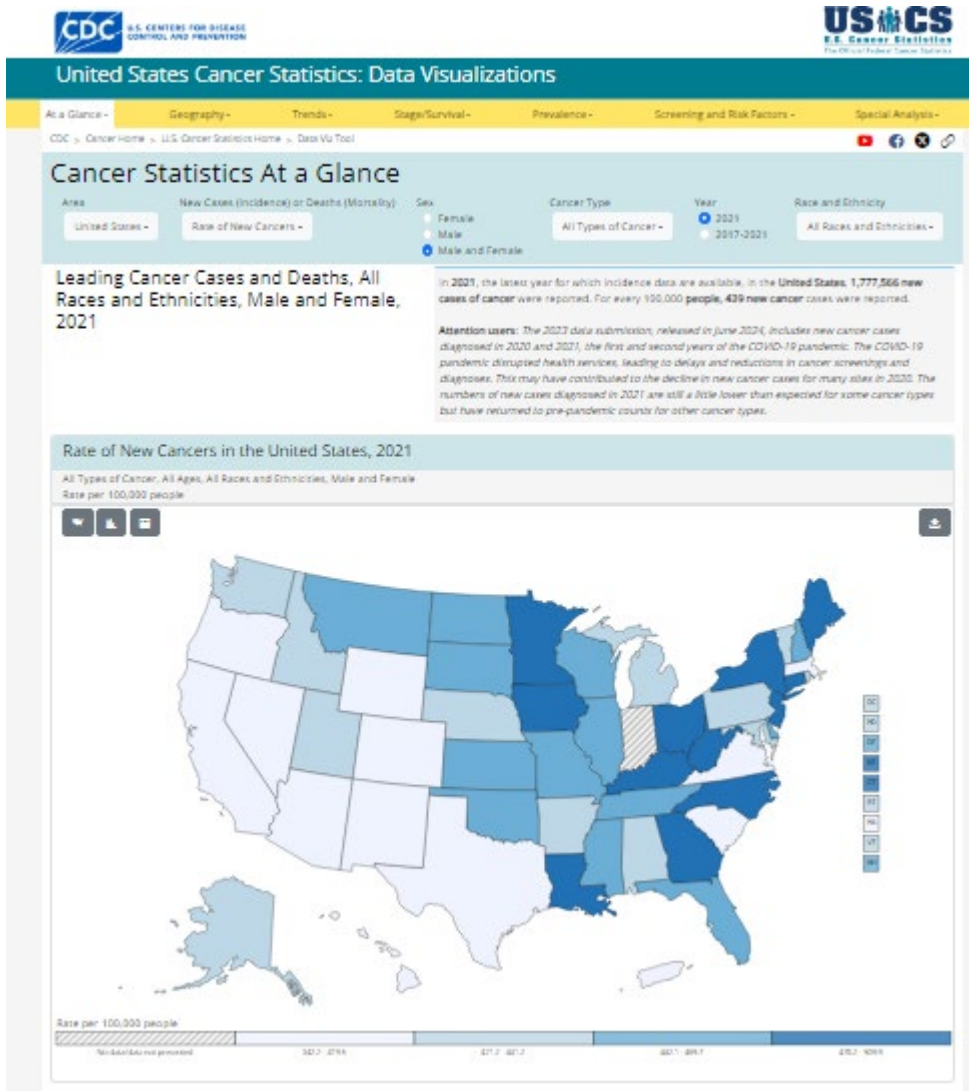
- All labs reporting electronically in real time using a common cloud platform
- Cloud platform will validate reports for conformance (structure and content)
- Conformance issues reported back to labs in real-time for continuous data improvement
- All labs are using the CAP protocols, and EHR/LIS can store and transmit SNOMED CT encoded data without any loss in content or meaning
- All CAP Cancer Protocols are using SNOMED codes
- Reports are used in real-time for cancer surveillance and research

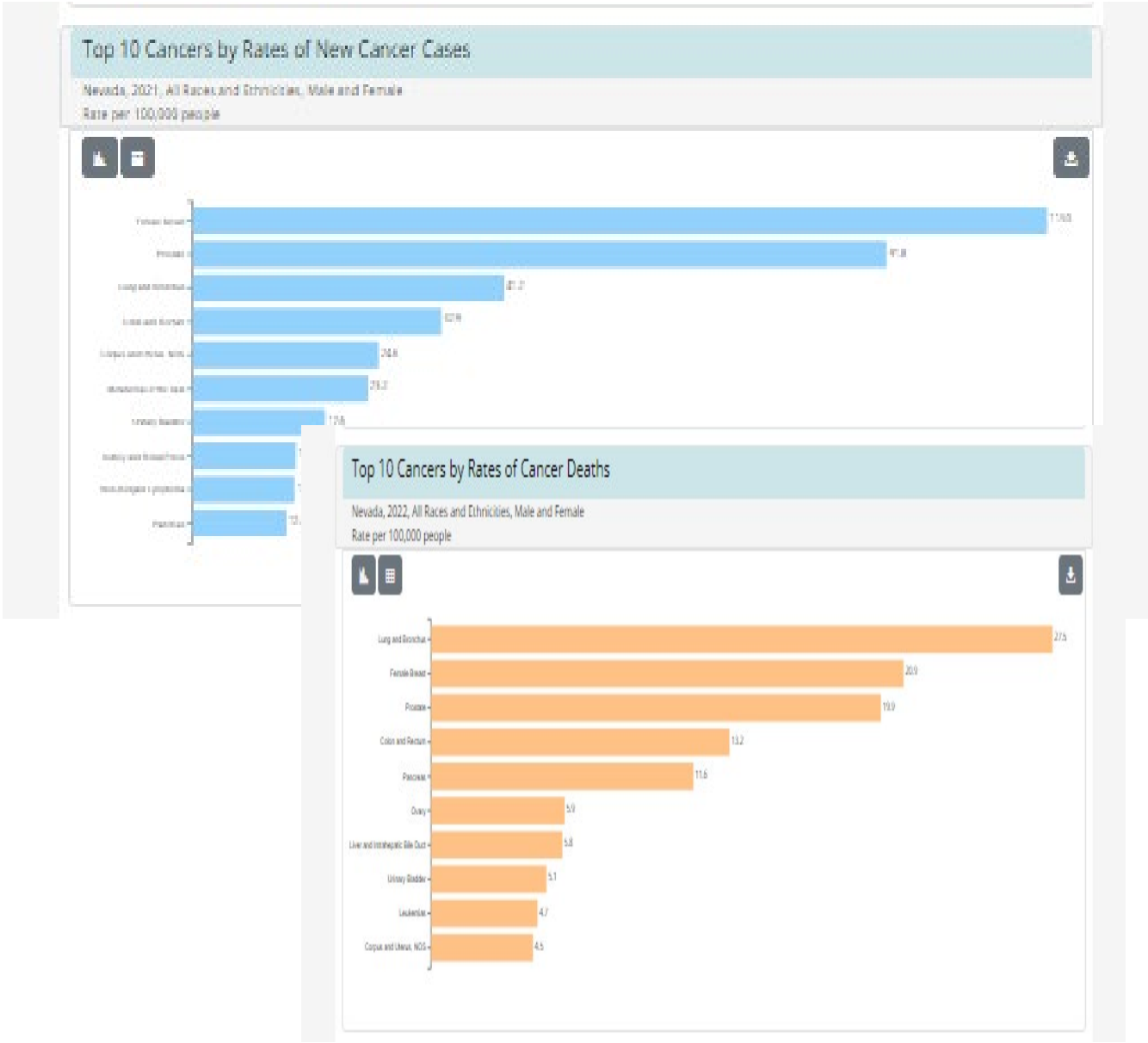
Cancer Registry Data Flow From APHL AIMS Cloud to CDC Cloud Platform



Data Visualizations Tool

U.S. Cancer Statistics

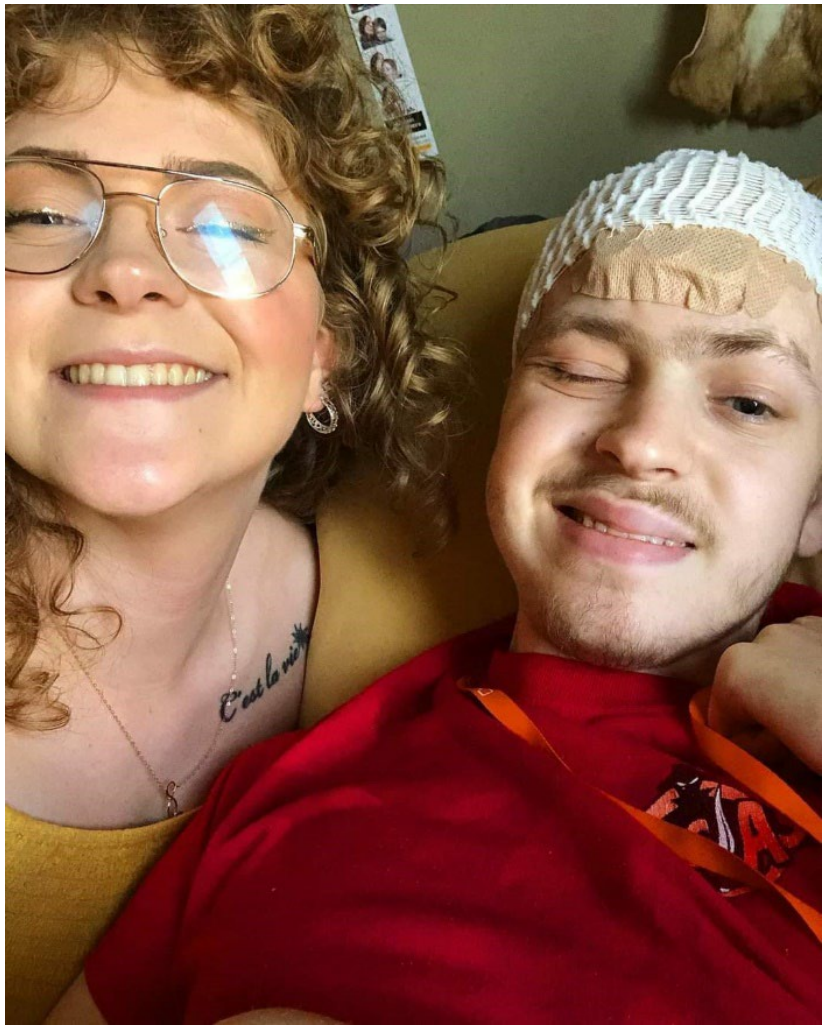




www.cdc.gov/uscs/dataviz

Benefits and Return on Investment for Patients, Providers, and Public Health

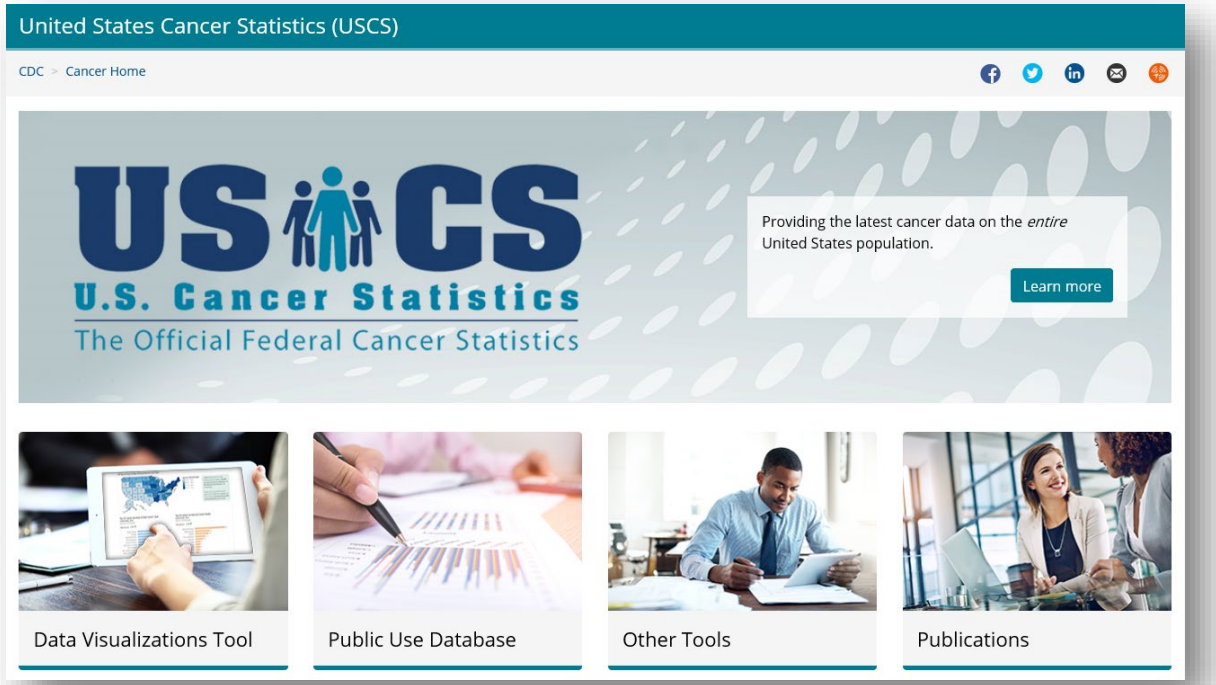
- **Enable faster reporting of all cancer cases**
  - ❖ Including childhood and young adult cancers
- **Identify which interventions work**
- **Inform resource allocation**
- **Identify research priorities more quickly**
- **Timely identification for clinical trials**



Resources

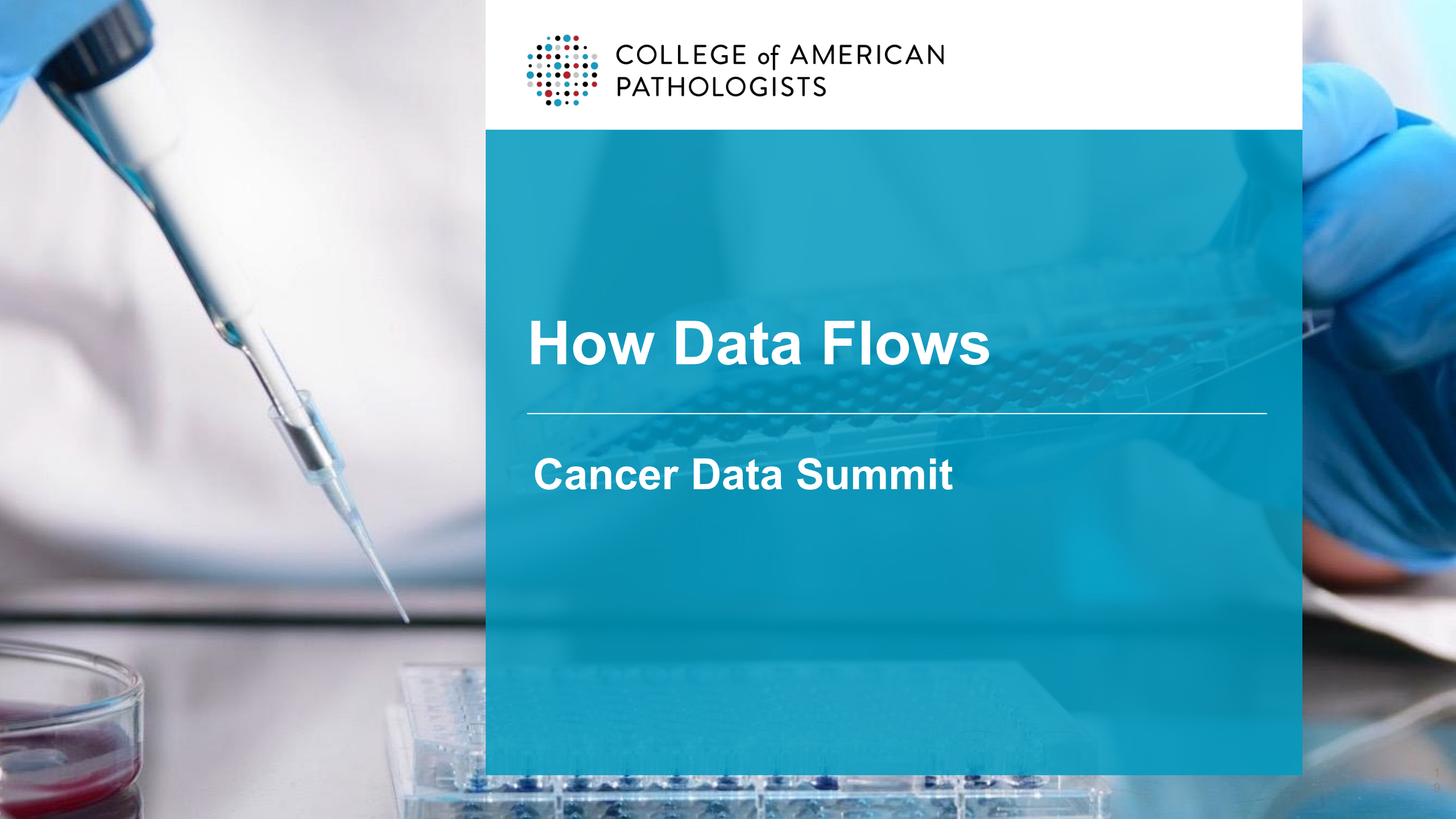
- CDC National Program of Cancer Registries: https://www.cdc.gov/national-program-cancer-registries/
- HL7 FHIR Cancer Pathology Data Sharing Implementation guide: https://build.fhir.org/ig/HL7/cancer-reporting/
- HL7 FHIR Central Cancer Registry Reporting Implementation Guide: https://build.fhir.org/ig/HL7/fhir-central-cancer-registry-reporting-ig/index.html
- North American Association of Central Cancer Registries (NAACCR) Electronic Pathology Reporting Guideline: https://www.naaccr.org/pathology-laboratory-electronic-reporting/
- Association of Public Health Laboratories Informatics Messaging Services: https://www.aphl.org/programs/informatics/Pages/aims_platform.aspx
- EHR Certification: https://www.healthit.gov/topic/certification-ehrs/certification-health-it
- United States Core Data for Interoperability (USCDI): https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi
- US Core Implementation Guide: https://build.fhir.org/ig/HL7/US-Core/
- USCDI+ Cancer: https://uscdiplus.healthit.gov/uscdi
- Minimum Common Oncology Data Elements (mCODE): https://confluence.hl7.org/display/COD/mCODE
- Common Oncology Data Elements eXtensions (CodeX) HL7 FHIR Accelerator: https://confluence.hl7.org/display/COD/Cancer+Registry+Reporting

Thank You!



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 cdc.gov
Follow us on X (Twitter) @CDCgov & @CDC_cancer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U. S. Centers for Disease Control and Prevention.



COLLEGE of AMERICAN PATHOLOGISTS

How Data Flows

Cancer Data Summit

Alex Goel

COI Declaration

- Co-Owner of Topology Health
- Consultant for The College of American Pathologists (CAP) working on projects related to Award Agreement Number 1 NU58DP007573-01-00 from the CDC

We’re Collecting Vast Amounts of Data in Healthcare

This data is useful in many contexts

Cancer Pathology Data Sharing

Specimen
- **Procedure:** Lobectomy
- **Specimen Laterality:** Right

Tumor
- **Tumor Site:** Lower lobe of lung
- **Histologic Type:** Predominantly squamous cell carcinoma, moderately to poorly-differentiated; focal sarcomatoid carcinoma component.
- **Histologic Grade:** G3: Poorly differentiated
- **Total Tumor Size (size of entire tumor):** 2.2 x 1.6 x 1.2 Centimeters (cm)
- **Tumor Focality:** Single focus
- **Visceral Pleura Invasion:** Not identified
- **Direct Invasion of Adjacent Structures:** Adjacent structures present but not involved
- **Treatment Effect:** No known presurgical therapy
- **Lymphovascular Invasion:** Cannot be determined

Margins
- **Margins:** All margins are uninvolved by tumor
  - **Margins Examined:** Bronchial; Vascular; Parenchymal
  - **Distance of Invasive Carcinoma from Closest Margin (Centimeters):** 8.5 cm
    - **Closest Margin:** Bronchial; Vascular

Lymph Nodes
- **Number of Lymph Nodes Involved:** 0
- **Number of Lymph Nodes Examined:** 13
  - **Nodal Stations Examined:** Cannot be determined

Pathologic Stage Classification (pTNM, AJCC 8th Edition)
- **Primary Tumor (pT):** pT1c
- **Regional Lymph Nodes (pN):** pN0

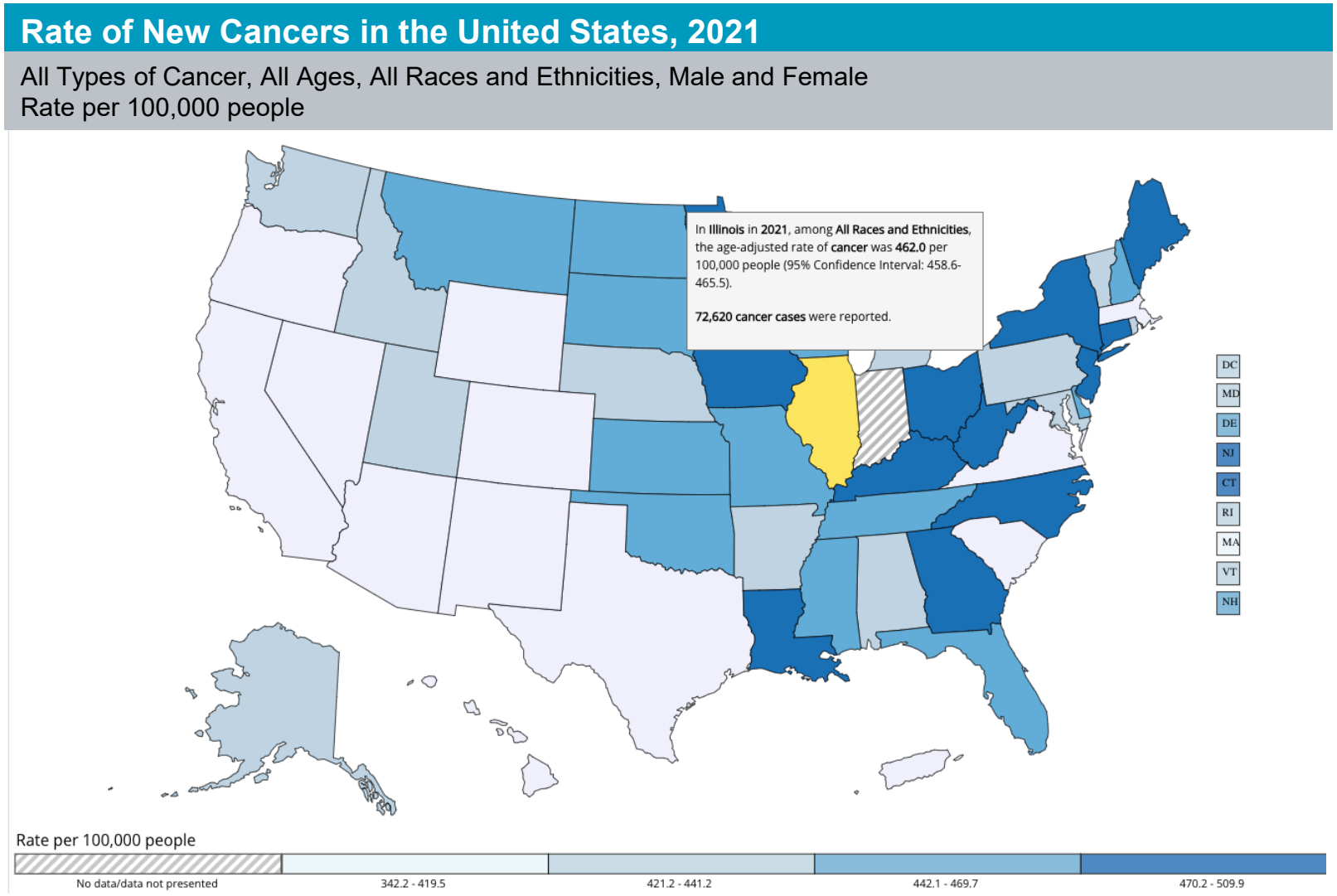
Additional Findings
- **Additional Findings:** Inflammation (type) - patchy acute; Emphysema; There is a usual interstitial pneumonia pattern in the background pulmonary parenchyma. This is characterized mostly by patchy areas of old interstitial fibrosis, with occasional fibroblastic foci and interstitial chronic inflammation, alternating with adjacent areas of normal alveolar septa - i.e. temporal heterogeneity. Subpleural involvement is more advanced, with some honeycombing. No asbestos bodies are found. While idiopathic pulmonary fibrosis is a consideration, clinical correlation is required.

Comments

Although the squamous carcinoma is invasive, there is a significant component that is apparently in situ, growing along small bronchioles or bronchiolized airways and alveolar spaces.

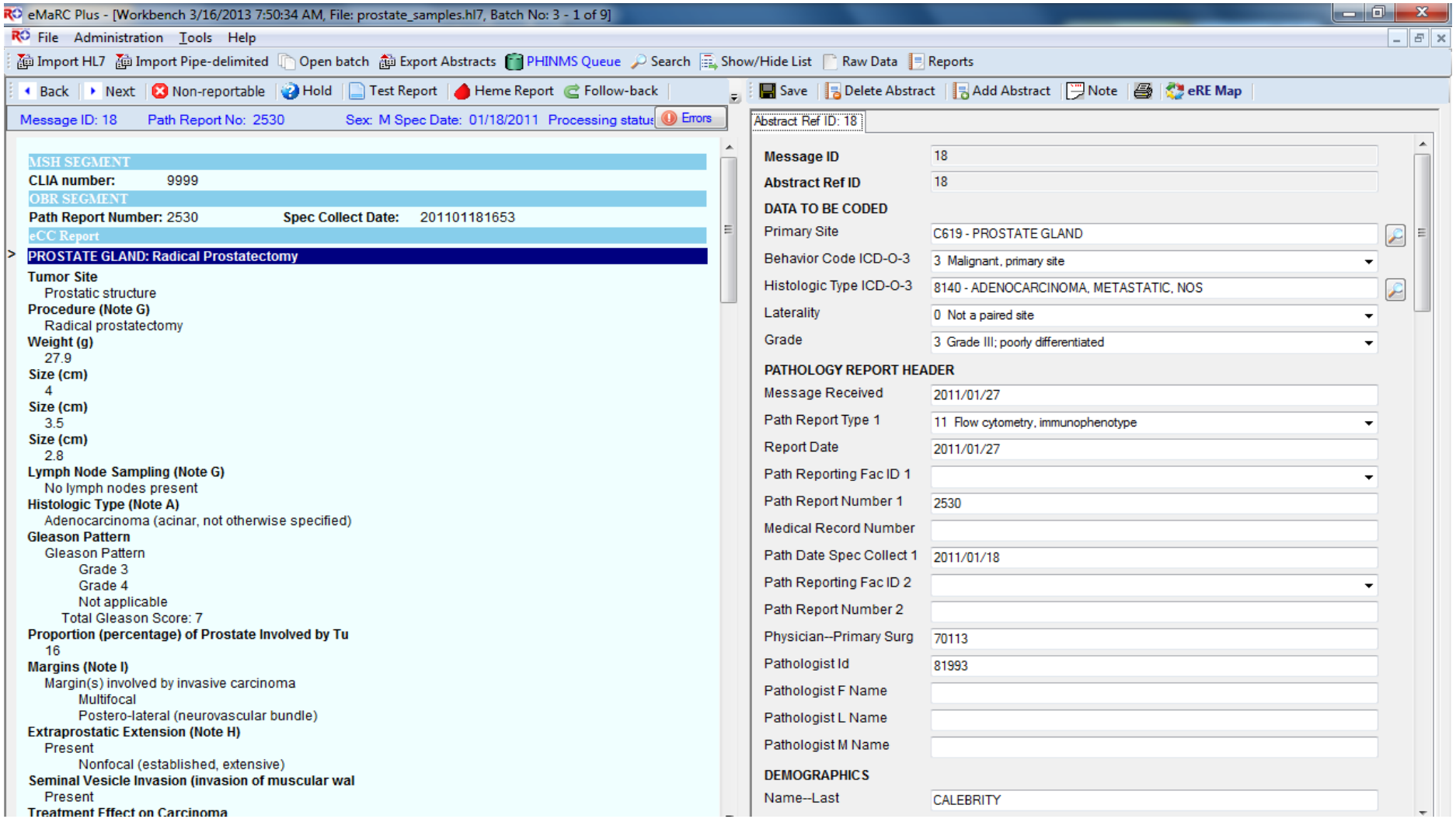
```
{
  "resourceType" : "Observation",
  "id" : "13",
  "meta" : {
    "versionId" : "1",
    "lastUpdated" : "2021-09-15T16:14:06.548Z",
    "profile" : [ ...
    ]
  },
  "text" : { ...
  },
  "identifier" : [
    { ...
    }
  ],
  "status" : "final",
  "code" : {
    "coding" : [
      {
        "system" : "https://CAP.org/eCC",
        "code" : "41794.100004300",
        "display" : "Histologic Type (Note D)"
      }
    ]
  },
  "subject" : { ...
  },
  "performer" : [ ...
  ],
  "valueCodeableConcept" : {
    "coding" : [
      {
        "system" : "https://CAP.org/eCC",
        "code" : "16280.100004300",
        "display" : "Invasive carcinoma of no special type (ductal)"
      },
      {
        "system" : "http://snomed.info/sct",
        "code" : "408643008",
        "display" : "Infiltrating duct carcinoma of breast"
      }
    ]
  },
  "specimen" : {
    "reference" : "Specimen/specimen875758333"
  }
}
```

Where does all this data go?

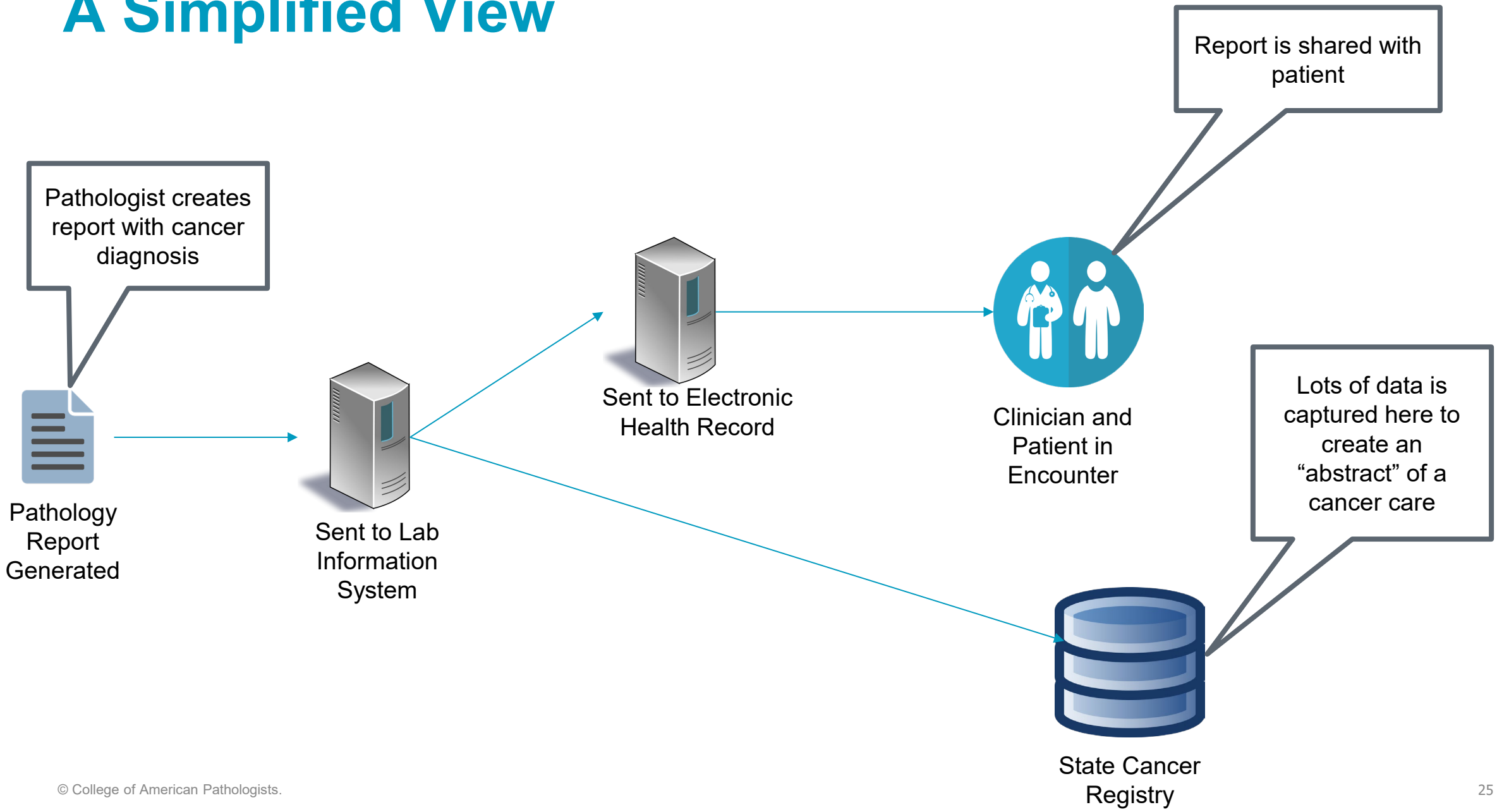


https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/

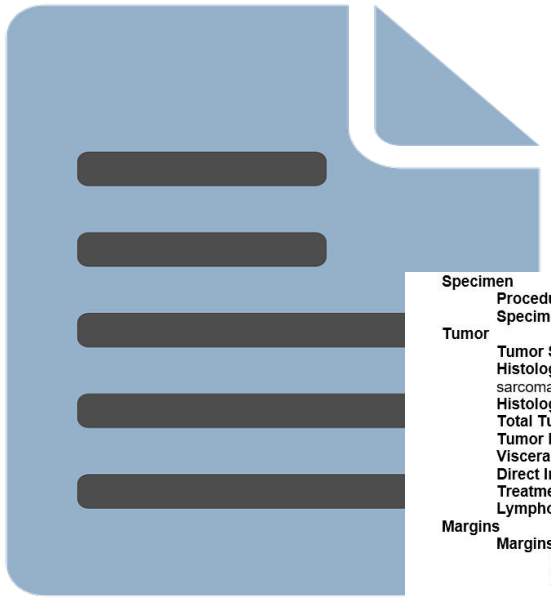
Registry Software – eMaRC Plus



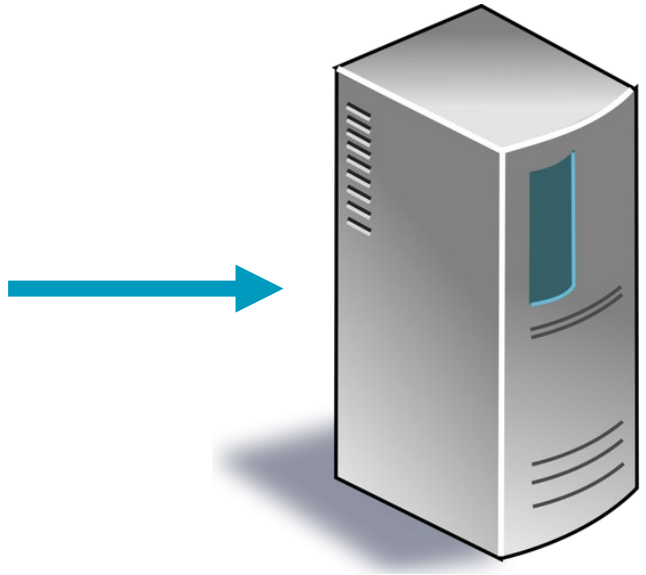
A Simplified View



The e-Paper Problem



Specimen
Procedure: Lobectomy
Specimen Laterality: Right
Tumor
Tumor Site: Lower lobe of lung
Histologic Type: Predominantly squamous cell carcinoma, moderately to poorly-differentiated; focal sarcomatoid carcinoma component.
Histologic Grade: G3: Poorly differentiated
Total Tumor Size (size of entire tumor): 2.2 x 1.6 x 1.2 Centimeters (cm)
Tumor Focality: Single focus
Visceral Pleura Invasion: Not identified
Direct Invasion of Adjacent Structures: Adjacent structures present but not involved
Treatment Effect: No known presurgical therapy
Lymphovascular Invasion: Cannot be determined
Margins
Margins: All margins are uninvolved by tumor
Margins Examined: Bronchial; Vascular; Parenchymal
Distance of Invasive Carcinoma from Closest Margin (Centimeters): 8.5 cm
Closest Margin: Bronchial; Vascular
Lymph Nodes
Number of Lymph Nodes Involved: 0
Number of Lymph Nodes Examined: 13
Nodal Stations Examined: Cannot be determined
Pathologic Stage Classification (pTNM, AJCC 8th Edition)
Primary Tumor (pT): pT1c
Regional Lymph Nodes (pN): pN0
Additional Findings
Additional Findings: Inflammation (type) - patchy acute; Emphysema; There is a usual interstitial pneumonia pattern in the background pulmonary parenchyma. This is characterized mostly by patchy areas of old interstitial fibrosis, with occasional fibroblastic foci and interstitial chronic inflammation, alternating with adjacent areas of normal alveolar septa - i.e. temporal heterogeneity. Subpleural involvement is more advanced, with some honeycombing. No asbestos bodies are found. While idiopathic pulmonary fibrosis is a consideration, clinical correlation is required.
Comments
Although the squamous carcinoma is invasive, there is a significant component that is apparently in situ, growing along small bronchioles or bronchiolized airways and alveolar spaces.

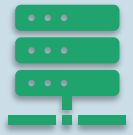


Digital Health Standards Enable Data To Flow

They’re the specifications for the “plumbing” that makes data flow

Why Does Cancer Data Need Standards?

Standards help everyone speak the same language



Enable users of electronic Cancer Protocols (eCPs) to share the structured data created

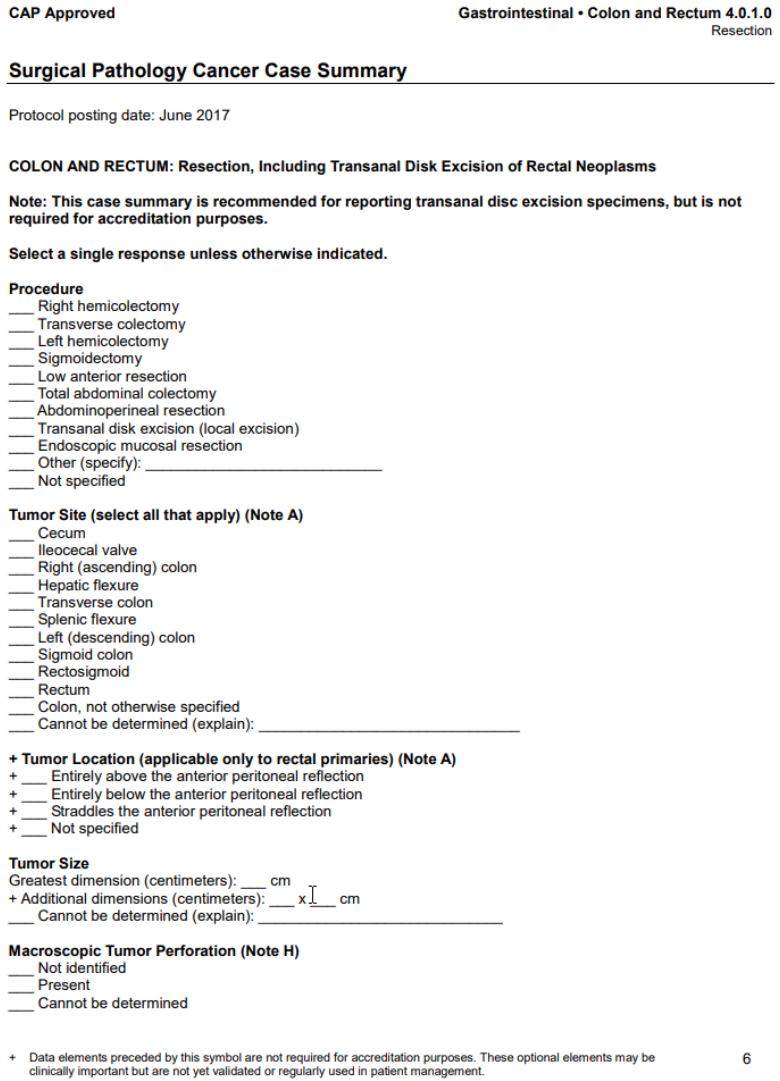
Ensuring that pathologists and users of pathology data, including Cancer Registries, have high quality data

Synoptic Reporting in Cancer Pathology

electronic Cancer Protocols and their role in supporting Cancer Registries

What are the CAP Cancer Protocols?

- Compilation of standards
  - American Joint Committee on Cancer (AJCC) Staging System (2020)
  - World Health Organization (WHO) Blue Books
  - International Classifications of Disease for Oncology (ICD-O-3)
  - Evidence based practice guidelines
- Provide cancer reporting core data elements
- www.cap.org/cancerprotocols



CAP Approved **Gastrointestinal • Colon and Rectum 4.0.1.0**
Resection

Surgical Pathology Cancer Case Summary

Protocol posting date: June 2017

COLON AND RECTUM: Resection, Including Transanal Disk Excision of Rectal Neoplasms

Note: This case summary is recommended for reporting transanal disc excision specimens, but is not required for accreditation purposes.

Select a single response unless otherwise indicated.

Procedure
___ Right hemicolectomy
___ Transverse colectomy
___ Left hemicolectomy
___ Sigmoidectomy
___ Low anterior resection
___ Total abdominal colectomy
___ Abdominoperineal resection
___ Transanal disk excision (local excision)
___ Endoscopic mucosal resection
___ Other (specify): _____
___ Not specified

Tumor Site (select all that apply) (Note A)
___ Cecum
___ Ileocecal valve
___ Right (ascending) colon
___ Hepatic flexure
___ Transverse colon
___ Splenic flexure
___ Left (descending) colon
___ Sigmoid colon
___ Rectosigmoid
___ Rectum
___ Colon, not otherwise specified
___ Cannot be determined (explain): _____

+ Tumor Location (applicable only to rectal primaries) (Note A)
+ ___ Entirely above the anterior peritoneal reflection
+ ___ Entirely below the anterior peritoneal reflection
+ ___ Straddles the anterior peritoneal reflection
+ ___ Not specified

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

Macroscopic Tumor Perforation (Note H)
___ Not identified
___ Present
___ Cannot be determined

+ Data elements preceded by this symbol are not required for accreditation purposes. These optional elements may be clinically important but are not yet validated or regularly used in patient management. 6

What Are the electronic Cancer Protocols (eCPs)?

Specimen
- **Procedure:** Lobectomy
- **Specimen Laterality:** Right

Tumor
- **Tumor Site:** Lower lobe of lung
- **Histologic Type:** Predominantly squamous cell carcinoma, moderately to poorly-differentiated; focal sarcomatoid carcinoma component.
- **Histologic Grade:** G3: Poorly differentiated
- **Total Tumor Size (size of entire tumor):** 2.2 x 1.6 x 1.2 Centimeters (cm)
- **Tumor Focality:** Single focus
- **Visceral Pleura Invasion:** Not identified
- **Direct Invasion of Adjacent Structures:** Adjacent structures present but not involved
- **Treatment Effect:** No known presurgical therapy
- **Lymphovascular Invasion:** Cannot be determined

Margins
- **Margins:** All margins are uninvolved by tumor
  - **Margins Examined:** Bronchial; Vascular; Parenchymal
  - **Distance of Invasive Carcinoma from Closest Margin (Centimeters):** 8.5 cm
    - **Closest Margin:** Bronchial; Vascular

Lymph Nodes
- **Number of Lymph Nodes Involved:** 0
- **Number of Lymph Nodes Examined:** 13
  - **Nodal Stations Examined:** Cannot be determined

Pathologic Stage Classification (pTNM, AJCC 8th Edition)
- **Primary Tumor (pT):** pT1c
- **Regional Lymph Nodes (pN):** pN0

Additional Findings
- **Additional Findings:** Inflammation (type) - patchy acute; Emphysema; There is a usual interstitial pneumonia pattern in the background pulmonary parenchyma. This is characterized mostly by patchy areas of old interstitial fibrosis, with occasional fibroblastic foci and interstitial chronic inflammation, alternating with adjacent areas of normal alveolar septa - i.e. temporal heterogeneity. Subpleural involvement is more advanced, with some honeycombing. No asbestos bodies are found. While idiopathic pulmonary fibrosis is a consideration, clinical correlation is required.

Comments

Although the squamous carcinoma is invasive, there is a significant component that is apparently in situ, growing along small bronchioles or bronchiolized airways and alveolar spaces.

Computerized versions of the cancer protocols

eCPs can automate information sharing and make it possible to do more with the data

https://www.cap.org/laboratory-improvement/proficiency-testing/cap-efrm

NAACCR Vol V Message Reference

```
MSH|^~\&||xxx^1234^CLIA|||1235||ORU^R01^ORU_R01|12|P|2.5.1|
OBX|1|ST|60573-3^Report template source^LN||CAP eCC||||||F|||202001021400
OBX|2|CWE|60572-5^Report template ID^LN||119.100004300^LUNG^CAPECC||||||F|||202001021400
OBX|3|ST|60574-1^Report template version ID^LN||3.005.001||||||F|||202001021400
OBX|4|CWE|43094.100004300^?Synchronous Tumors (required if morphologically distinct unrelated multiple primary tumors are present)^CAPECC||41654.100004300^?Not applicable^CAPECC||||||F|||2020(
OBX|5|CWE|55856.100004300^Procedure^CAPECC||15717.100004300^Bilobectomy^CAPECC||||||F|||202001021400
OBX|6|CWE|1693.100004300^Specimen Laterality^CAPECC||1694.100004300^Right^CAPECC||||||F|||202001021400
OBX|7|CWE|54193.100004300^Tumor Site^CAPECC||1699.100004300^Middle lobe of lung^CAPECC||||||F|||202001021400
OBX|8|CWE|54193.100004300^Tumor Site^CAPECC||1700.100004300^Lower lobe of lung^CAPECC||||||F|||202001021400
OBX|9|CWE|41746.100004300^Histologic Type (Note C)^CAPECC||33378.100004300^Colloid adenocarcinoma^CAPECC||||||F|||202001021400
OBX|10|CWE|1731.100004300^Histologic Grade (Note D)^CAPECC||1732.100004300^Not applicable^CAPECC||||||F|||202001021400
OBX|11|CWE|43111.100004300^Total Tumor Size (size of entire tumor)#^CAPECC||43137.100004300^Cannot be determined^CAPECC||||||F|||202001021400
OBX|12|ST|43111.100004300^Total Tumor Size (size of entire tumor)#^CAPECC|43137|Cannot Reapproximate||||||F|||202001021400
OBX|13|CWE|41688.100004300^?Size of Invasive Component## (required only if invasive nonmucinous adenocarcinomas with lepidic component is present)^CAPECC||41820.100004300^?Not applicable^CAPE(
OBX|14|CWE|41711.100004300^Tumor Focality (Note B)^CAPECC||41731.100004300^Cannot be determined^CAPECC||||||F|||202001021400
OBX|15|CWE|15671.100004300^Visceral Pleura Invasion (Note E)^CAPECC||15673.100004300^Not identified^CAPECC||||||F|||202001021400
OBX|16|CWE|43724.100004300^Direct Invasion of Adjacent Structures (Note G)^CAPECC||1775.100004300^Adjacent structures present but not involved^CAPECC||||||F|||202001021400
OBX|17|CWE|15684.100004300^Treatment Effect (Note I)^CAPECC||30013.100004300^No known presurgical therapy^CAPECC||||||F|||202001021400
OBX|18|CWE|1795.100004300^Lymphovascular Invasion (Note F)^CAPECC||1796.100004300^Not identified^CAPECC||||||F|||202001021400
OBX|19|CWE|46319.100004300^Margins^CAPECC||57726.100004300^One or more margins are involved by tumor, or any margin cannot be assessed^CAPECC||||||F|||202001021400
OBX|20|CWE|51508.100004300^Bronchial Margin^CAPECC||54582.100004300^Uninvolved by invasive carcinoma^CAPECC||||||F|||202001021400
OBX|21|CWE|40805.100004300^?Status of Carcinoma in Situ at Bronchial Margin^CAPECC||56514.100004300^?Not applicable^CAPECC||||||F|||202001021400
OBX|22|CWE|40624.100004300^Vascular Margin^CAPECC||59983.100004300^Uninvolved by carcinoma^CAPECC||||||F|||202001021400
OBX|23|CWE|46180.100004300^Parenchymal Margin^CAPECC||16055.100004300^Positive for invasive carcinoma^CAPECC||||||F|||202001021400
OBX|24|CWE|7841.100004300^Number of Lymph Nodes Involved^CAPECC||14471.100004300^None identified^CAPECC||||||F|||202001021400
OBX|25|CWE|33444.100004300^Number of Lymph Nodes Examined^CAPECC||7835.100004300^Specify number^CAPECC||||||F|||202001021400
OBX|26|NM|33444.100004300^Number of Lymph Nodes Examined^CAPECC|7835|2||||||F|||202001021400
OBX|27|CWE|33450.100004300^Nodal Stations Examined^CAPECC||55956.100004300^Cannot be determined^CAPECC||||||F|||202001021400
OBX|28|CWE|15994.100004300^?TNM Descriptors^CAPECC||2027.100004300^?Not applicable^CAPECC||||||F|||202001021400
```

A NAACCR Vol message containing Questions and Answers from the eCP filled out by a Pathologist which is sent

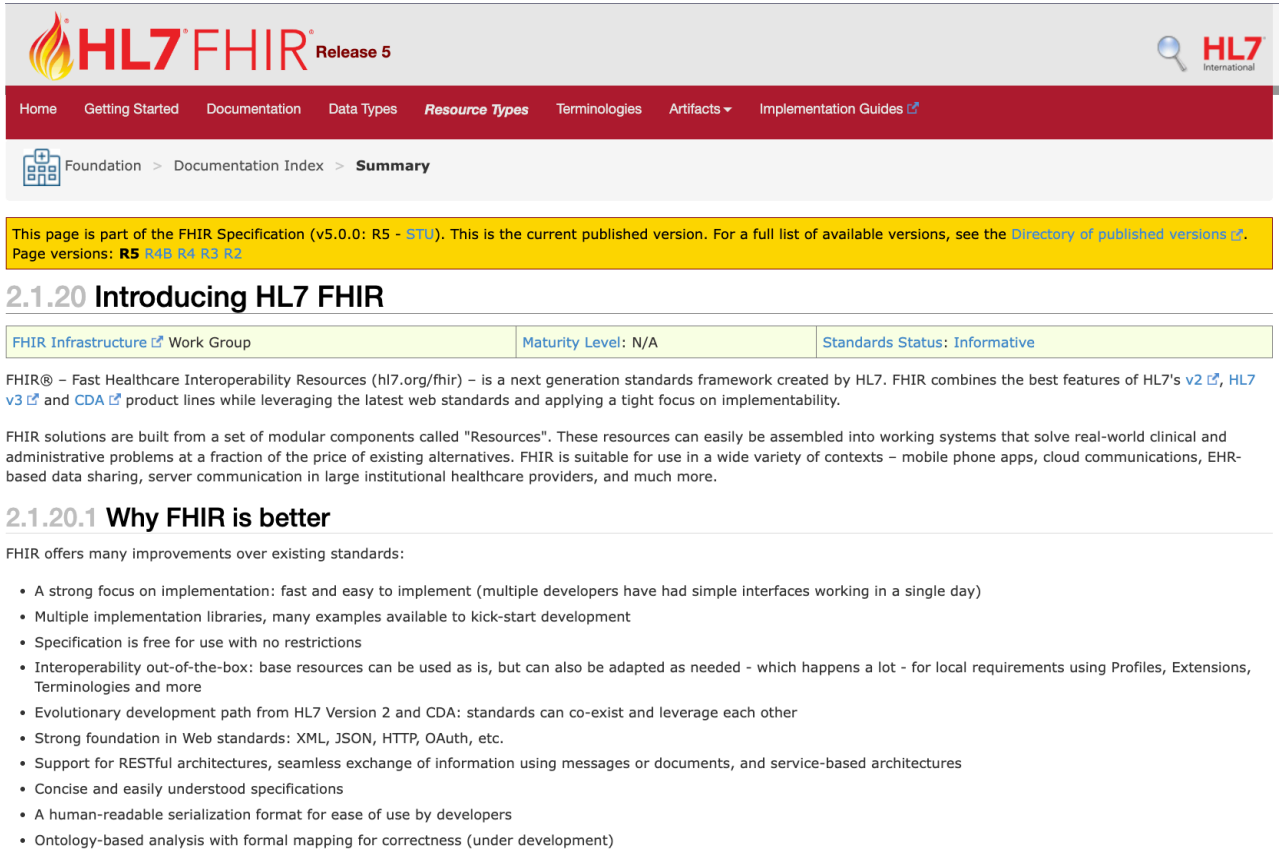
This message is sent to a cancer registry

Cancer Pathology Data Sharing

An Implementation Guide on Using FHIR for Pathology Cancer Data Exchange

What is FHIR

- “FHIR solutions are built from a set of modular components called "Resources".
- These resources can easily be assembled into working systems that solve real-world clinical and administrative problems.”



HL7 FHIR Release 5 | HL7 International

Home | Getting Started | Documentation | Data Types | *Resource Types* | Terminologies | Artifacts | Implementation Guides

Foundation > Documentation Index > **Summary**

This page is part of the FHIR Specification (v5.0.0: R5 - STU). This is the current published version. For a full list of available versions, see the Directory of published versions.
Page versions: **R5** R4B R4 R3 R2

2.1.20 Introducing HL7 FHIR

FHIR Infrastructure Work Group	Maturity Level: N/A	Standards Status: Informative

FHIR® – Fast Healthcare Interoperability Resources (hl7.org/fhir) – is a next generation standards framework created by HL7. FHIR combines the best features of HL7's v2, HL7 v3 and CDA product lines while leveraging the latest web standards and applying a tight focus on implementability.

FHIR solutions are built from a set of modular components called "Resources". These resources can easily be assembled into working systems that solve real-world clinical and administrative problems at a fraction of the price of existing alternatives. FHIR is suitable for use in a wide variety of contexts – mobile phone apps, cloud communications, EHR-based data sharing, server communication in large institutional healthcare providers, and much more.

2.1.20.1 Why FHIR is better

FHIR offers many improvements over existing standards:

- A strong focus on implementation: fast and easy to implement (multiple developers have had simple interfaces working in a single day)
- Multiple implementation libraries, many examples available to kick-start development
- Specification is free for use with no restrictions
- Interoperability out-of-the-box: base resources can be used as is, but can also be adapted as needed - which happens a lot - for local requirements using Profiles, Extensions, Terminologies and more
- Evolutionary development path from HL7 Version 2 and CDA: standards can co-exist and leverage each other
- Strong foundation in Web standards: XML, JSON, HTTP, OAuth, etc.
- Support for RESTful architectures, seamless exchange of information using messages or documents, and service-based architectures
- Concise and easily understood specifications
- A human-readable serialization format for ease of use by developers
- Ontology-based analysis with formal mapping for correctness (under development)

Introducing HL7 FHIR – FHIR Infrastructure Group, 2024

Relationship to USCDI and USCDI+

- USCDI is designed to promote more consistent data
- Can be represented in FHIR using the US-Core Implementation Guide
- Cancer data has broader set belonging to USCDI+ Cancer

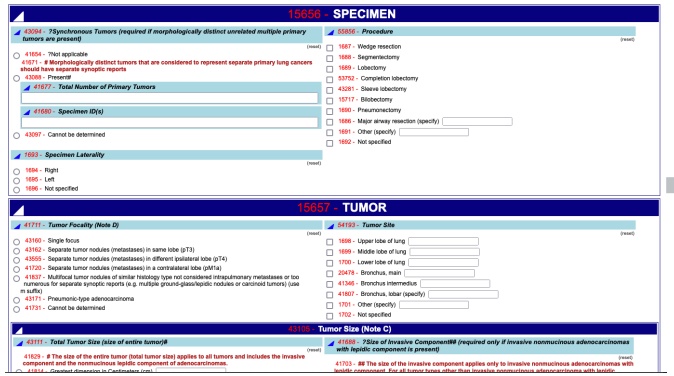
USCDI United States Core Data for Interoperability

United States Core Data for Interoperability

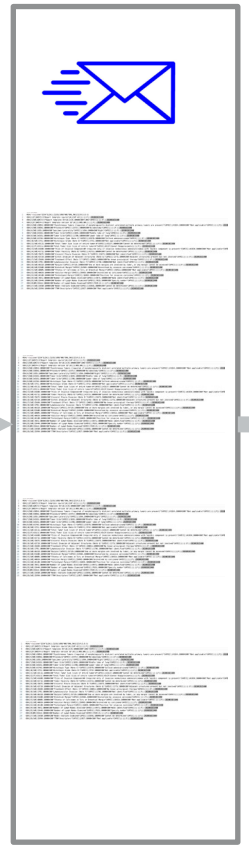
Version 5 | July 2024

This communication was printed, published, or produced and disseminated at U.S. taxpayer expense.

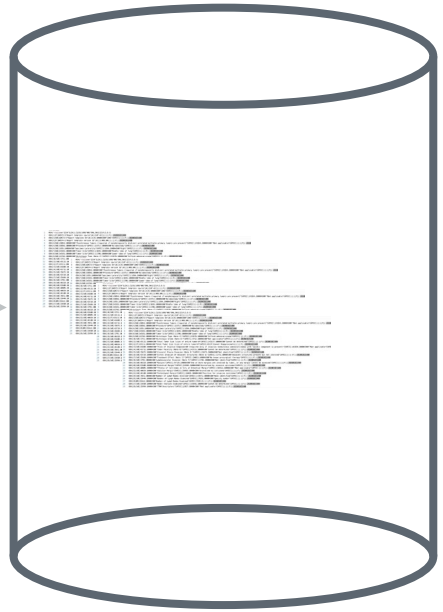
eCPs on FHIR + SNOMED



Filled eCP



Converted to FHIR



Saved as FHIR resources by the EMR

Endpoint could be *any receiver* (EMR, Registry, Health Information Exchange, etc.) who does not have the CKeys, but now they can understand the SNOMED

Getting to Computable Pathology Cancer Data

W. Scott Campbell, PhD, MBA
Peter Hinrichs Professor and Chair of Pathology Informatics
University of Nebraska Medical Center

University of Nebraska Medical Center

Nebraska Medicine

Disclosures

Nothing to disclose

What do we know?

Anatomic pathology reports contain critical information for:

- Patient care
- Clinical trials
- Public Health
- Quality of Care
- Research

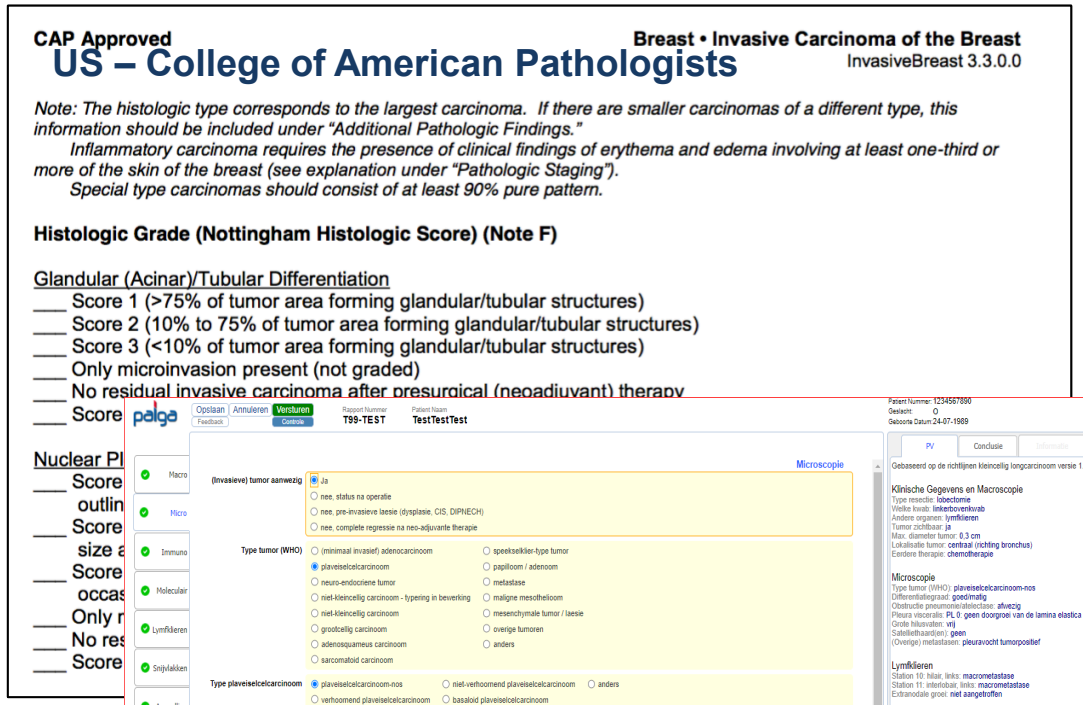
Stakeholders want and need this information

These data can be captured, shared (exchanged), used for multiple purposes repeatedly

HOW?

Part 1 - Structured Reporting

US – College of American Pathologists



CAP Approved

Breast • Invasive Carcinoma of the Breast

InvasiveBreast 3.3.0.0

Note: The histologic type corresponds to the largest carcinoma. If there are smaller carcinomas of a different type, this information should be included under "Additional Pathologic Findings."

Inflammatory carcinoma requires the presence of clinical findings of erythema and edema involving at least one-third or more of the skin of the breast (see explanation under "Pathologic Staging").

Special type carcinomas should consist of at least 90% pure pattern.

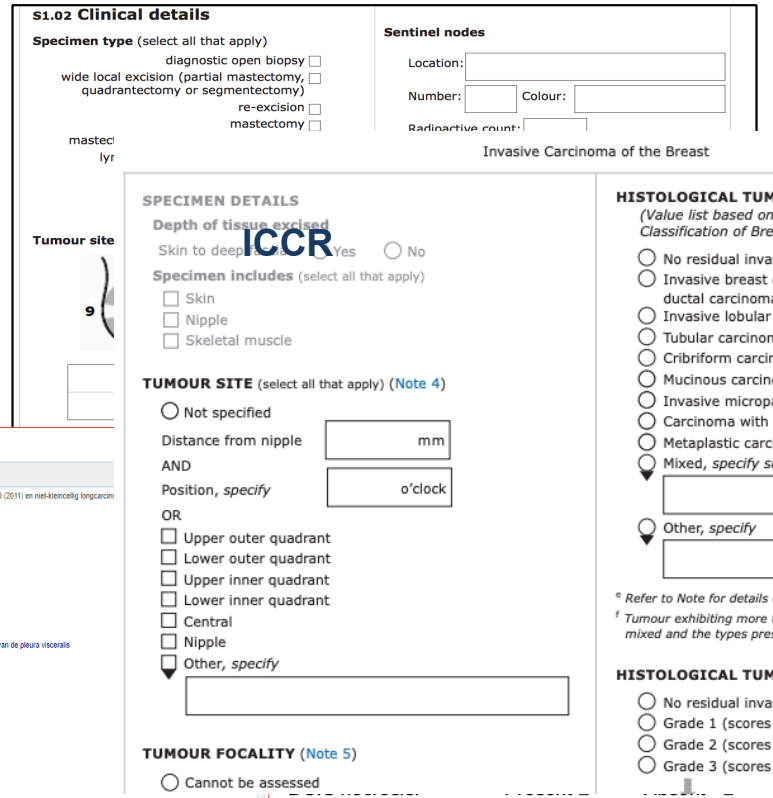
Histologic Grade (Nottingham Histologic Score) (Note F)

Glandular (Acinar)/Tubular Differentiation

___ Score 1 (>75% of tumor area forming glandular/tubular structures)
___ Score 2 (10% to 75% of tumor area forming glandular/tubular structures)
___ Score 3 (<10% of tumor area forming glandular/tubular structures)
___ Only microinvasion present (not graded)
___ No residual invasive carcinoma after presurgical (neoadjuvant) therapy
___ Score

Nuclear Pl
___ Score
outlin
___ Score
size a
___ Score
occas
___ Only r
___ No res
___ Score

Australasia- RCPA



S1.02 Clinical details

Specimen type (select all that apply)

diagnostic open biopsy ☐
wide local excision (partial mastectomy, quadrantectomy or segmentectomy) ☐
re-excision ☐
mastectomy ☐

Sentinel nodes

Location:
Number: Colour:
Radioactive count:

Invasive Carcinoma of the Breast

Tumour site

SPECIMEN DETAILS

Depth of tissue excised

Skin to deep ... Yes ○ No

Specimen includes (select all that apply)

☐ Skin
☐ Nipple
☐ Skeletal muscle

TUMOUR SITE (select all that apply) (Note 4)

○ Not specified
Distance from nipple mm
AND
Position, *specify* o'clock
OR
☐ Upper outer quadrant
☐ Lower outer quadrant
☐ Upper inner quadrant
☐ Lower inner quadrant
☐ Central
☐ Nipple
☐ Other, *specify*

TUMOUR FOCALITY (Note 5)

○ Cannot be assessed

ICCR

HISTOLOGICAL TUMOUR TYPE[c] (Note 7)

(Value list based on the World Health Organization Classification of Breast Tumours (2019))

○ No residual invasive carcinoma
○ Invasive breast carcinoma of no special type (invasive ductal carcinoma, not otherwise specified)[e]
○ Invasive lobular carcinoma
○ Tubular carcinoma
○ Cribriform carcinoma
○ Mucinous carcinoma
○ Invasive micropapillary carcinoma
○ Carcinoma with apocrine differentiation
○ Metaplastic carcinoma
○ Mixed, *specify subtypes present*[f]
○ Other, *specify*

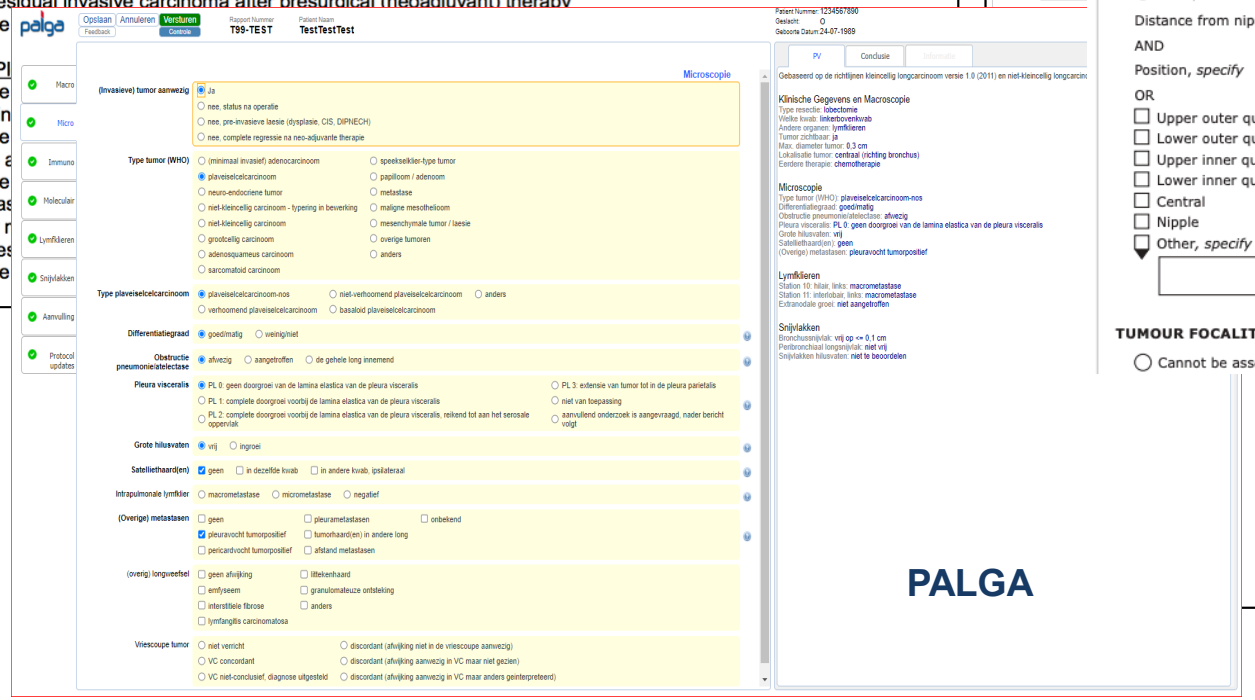
[e] *Refer to Note for details of variants including medullary carcinoma.*

[f] *Tumour exhibiting more than one tumour type should be designated mixed and the types present stated.*

HISTOLOGICAL TUMOUR GRADE (Note 8)

○ No residual invasive carcinoma
○ Grade 1 (scores of 3, 4, or 5)
○ Grade 2 (scores of 6 or 7)
○ Grade 3 (scores of 8 or 9)

PALGA



palga

Opslaan Annuleren Versturen

Rapport Nummer T99-TEST

Patient Naam TestTestTest

Microscopie

(Invasieve) tumor aanwezig: Ja; nee, status na operatie; nee, pre-invasieve laesie (dysplasie, CIS, DIPNECH); nee, complete regressie na neo-adjuvante therapie

Type tumor (WHO): (minimaal invasief) adenocarcinoom; papilloom / adenoom; neuro-endocriene tumor; metastase; niet-kleincellig carcinoom - typering in bewerking; maligne mesothelioom; niet-kleincellig carcinoom; mesenchymale tumor / laesie; grootcellig carcinoom; overige tumoren; adenosquameus carcinoom; anders; sarcomatoid carcinoom

Type plaveiselcelcarcinoom: plaveiselcelcarcinoom-nos; niet-verhoornend plaveiselcelcarcinoom; anders; verhoornend plaveiselcelcarcinoom; basaloid plaveiselcelcarcinoom

Differentiatiegraad: goed/matig; weinig/niet

Obstructie pneumonie/atelectase: afwezig; aangetroffen; de gehele long innemend

Pleura visceralis: PL 0: geen doorgroei van de lamina elastica van de pleura visceralis; PL 1: complete doorgroei voorbij de lamina elastica van de pleura visceralis; PL 2: complete doorgroei voorbij de lamina elastica van de pleura visceralis, reikend tot aan het serosale oppervlak; PL 3: extensie van tumor tot in de pleura parietalis; niet van toepassing; aanvullend onderzoek is aangevraagd, nader bericht volgt

Grote hilusvaten: vrij; ingroei

Satelliethaard(en): geen; in dezelfde kwab; in andere kwab, ipsilateraal

Intrapulmonale lymfklier: macrometastase; micrometastase; negatief

(Overige) metastasen: geen; pleurametastasen; onbekend; pleuravocht tumorpositief; tumorhaard(en) in andere long; pericardvocht tumorpositief; afstand metastasen

(overig) longweefsel: geen afwijking; littekenhaard; emfyseem; granulomateuze ontsteking; interstitiele fibrose; anders; lymfangitis carcinomatosa

Vriescoupe tumor: niet verricht; VC concordant; VC niet-conclusief, diagnose uitgesteld; discordant (afwijking niet in de vriescoupe aanwezig); discordant (afwijking aanwezig in VC maar niet gezien); discordant (afwijking aanwezig in VC maar anders geinterpreteerd)

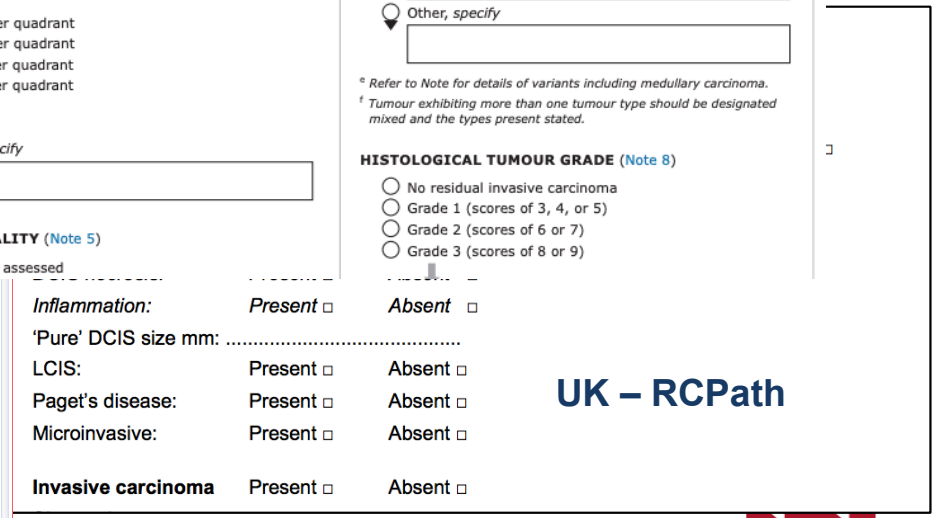
Klinische Gegevens en Macroscopie

Microscopie

Lymfklieren

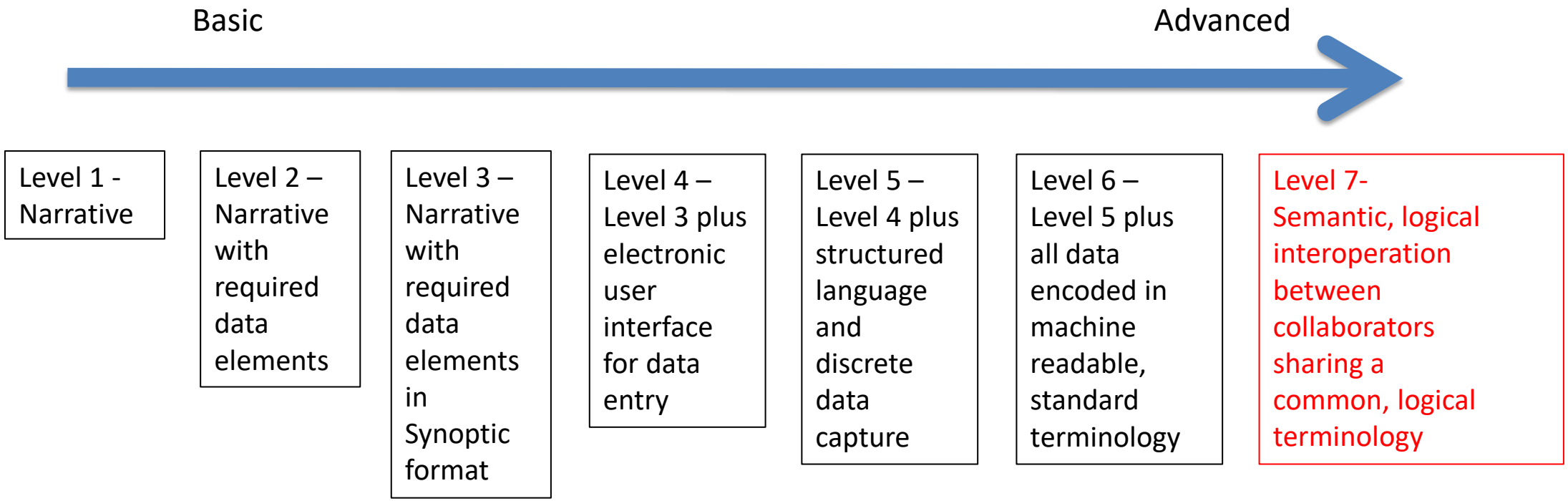
Snijvlakken

UK – RCPath



Inflammation:	*Present* ☐	*Absent* ☐
'Pure' DCIS size mm:		
LCIS:	Present ☐	Absent ☐
Paget's disease:	Present ☐	Absent ☐
Microinvasive:	Present ☐	Absent ☐
Invasive carcinoma	Present ☐	Absent ☐

Part 2 – The Data



1. Srigley JR, McGowan T, Maclean A, Raby M, Ross J, Kramer S, et al. Standardized synoptic cancer pathology reporting: a population-based approach. J Surg Oncol. 2009 Jun 15;99(8):517-24.

Part 2 - The Data Problem (prior to 2024)

•No standard representation of data elements to realize Level 6 or 7 reporting

•US CDC studies in 2005 and 2009 found that neither LOINC nor SNOMED CT had sufficient content with sufficient definition to unambiguously represent data elements in cancer registries for reliable query and study (Centers for Disease Control and Prevention. (2009). Report on the Reporting Pathology Protocols Project for Breast and Prostate Cancers and Melanomas Executive Summary.)

•US College of American Pathologists introduced C-keys after CDC report. C-keys are data element identifiers. They carry no meaning/semantic, but they do provide a mechanism to associated data elements to their appropriate protocols.

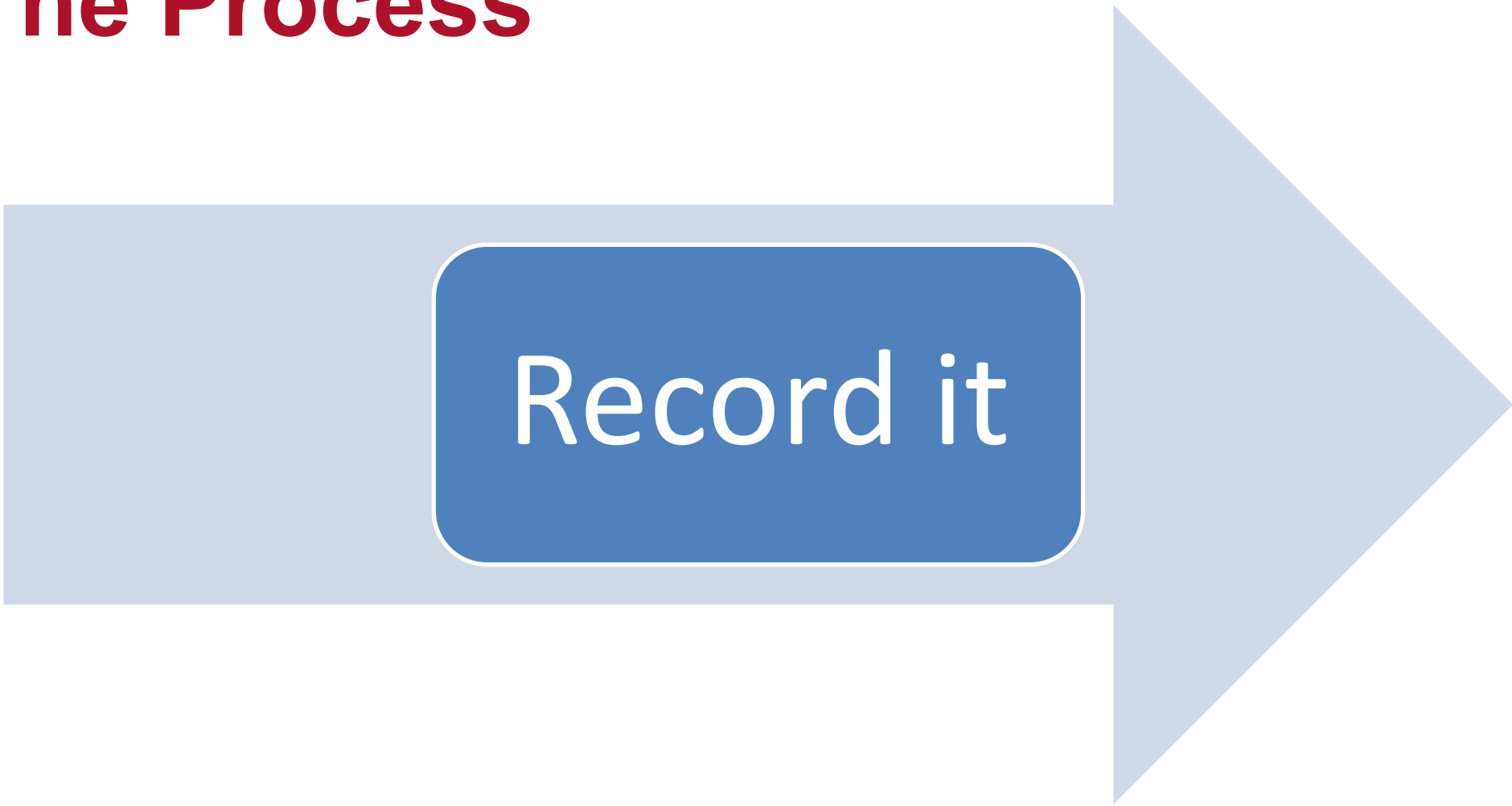
•The Cancer Synoptic Reporting Working Group (CSRWG) was established to address this problem within SNOMED CT

Part 2 – Data issue resolved

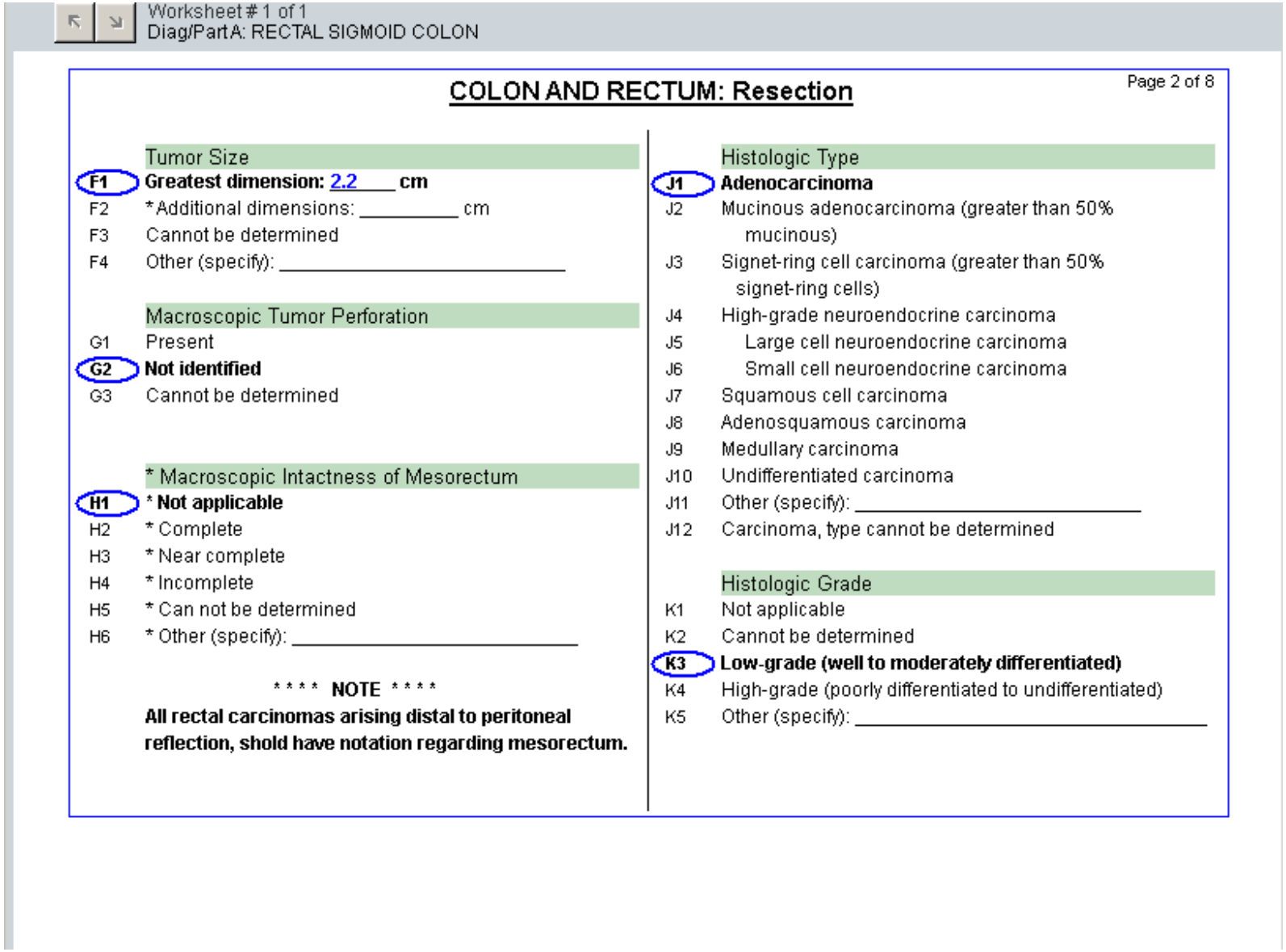
- 1284 new concepts created and/or fully modeled
- 100% of CAP required data elements for all solid tumors
  - 61 data sets
  - Includes both adult and pediatric data sets
  - CAP PERT committee reviewing and approving SNOMED CT terminology binding and association with C-keys.
  - CAP to include SNOMED CT terminology bindings in eCP and other release formats

- 24 ICCR data sets initially mapped to SNOMED CT
  - Terminology binding on-going for remaining data sets
  - Terminology binding to be reviewed and validated for use by ICCR

The Process



UNMC – Cerner Copath Example



Worksheet # 1 of 1
Diag/Part A: RECTAL SIGMOID COLON

COLON AND RECTUM: Resection

Tumor Size

F1 **Greatest dimension: 2.2 cm**
F2 *Additional dimensions: _____ cm
F3 Cannot be determined
F4 Other (specify): _____

Macroscopic Tumor Perforation

G1 Present
G2 **Not identified**
G3 Cannot be determined

* Macroscopic Intactness of Mesorectum

H1 *** Not applicable**
H2 * Complete
H3 * Near complete
H4 * Incomplete
H5 * Can not be determined
H6 * Other (specify): _____

****** NOTE ******

All rectal carcinomas arising distal to peritoneal reflection, shold have notation regarding mesorectum.

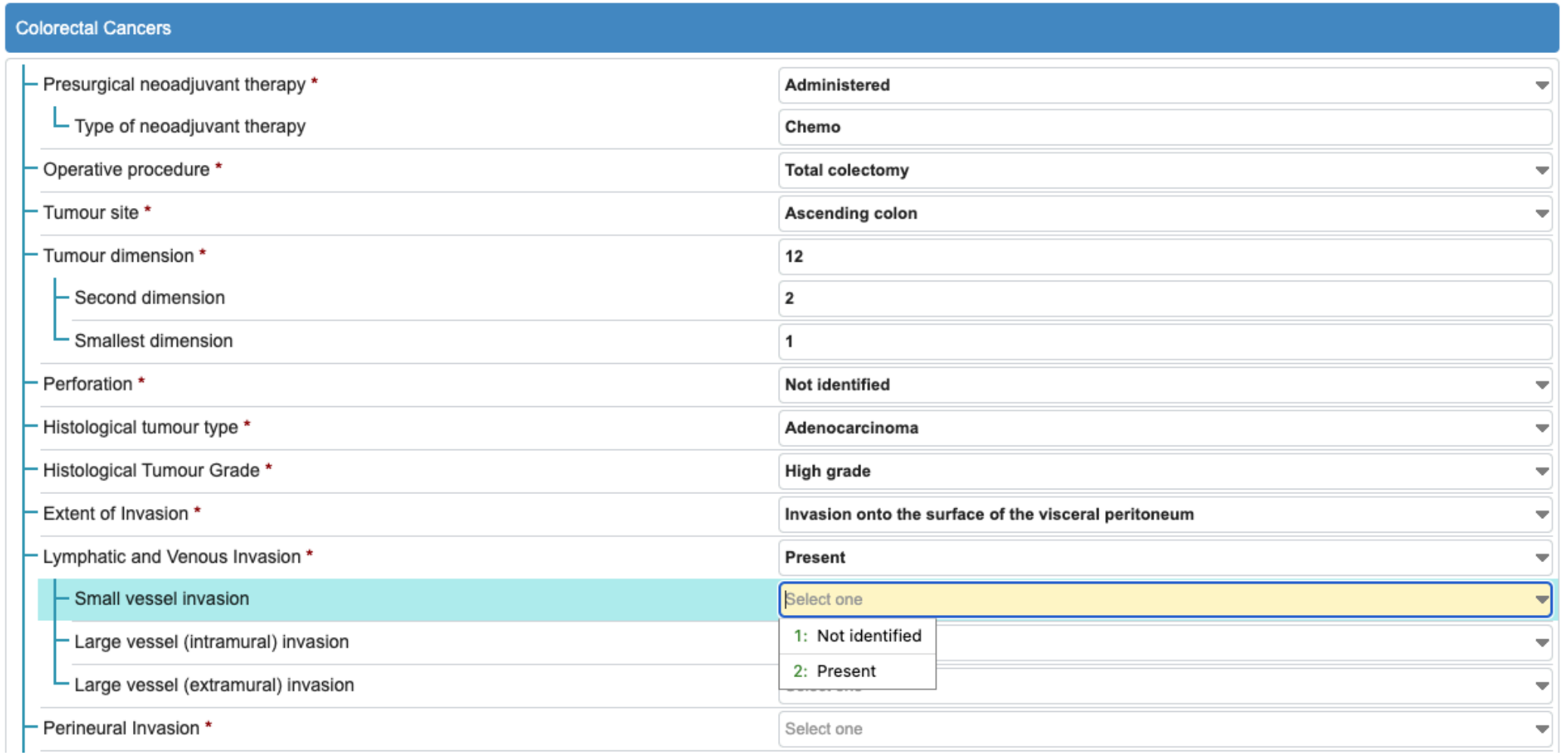
Histologic Type

J1 **Adenocarcinoma**
J2 Mucinous adenocarcinoma (greater than 50% mucinous)
J3 Signet-ring cell carcinoma (greater than 50% signet-ring cells)
J4 High-grade neuroendocrine carcinoma
J5 Large cell neuroendocrine carcinoma
J6 Small cell neuroendocrine carcinoma
J7 Squamous cell carcinoma
J8 Adenosquamous carcinoma
J9 Medullary carcinoma
J10 Undifferentiated carcinoma
J11 Other (specify): _____
J12 Carcinoma, type cannot be determined

Histologic Grade

K1 Not applicable
K2 Cannot be determined
K3 **Low-grade (well to moderately differentiated)**
K4 High-grade (poorly differentiated to undifferentiated)
K5 Other (specify): _____

Sample FHIR Questionnaire



Rendered by NLM tools:
https://lhcforms.nlm.nih.gov/lhcforms

The Process

FHIR SDC Format (partial)


```
{"resourceType": "QuestionnaireResponse",
….
    "authored": "2023-10-17T00:24:38.695Z",
    "item": [
        {"linkId": "8937332503874",
            "text": "Presurgical neoadjuvant therapy",
            "answer": [ { "valueCoding": {
                        "system": "http://snomed.info/sct/900000000000207008",
                        "code": "398166005",
                        "display": "Administered"},
                    "item": [ { "linkId": "7905003324223",
                            "text": "Type of neoadjuvant therapy",
                            "answer": [ { "valueString": "Chemo" }
```

HL7 v2 OBR and OBX segments

OBR|1|null^Colorectal Cancers|

OBX|1|CNE|1279827005^Presurgical neoadjuvant therapy^LN||398166005^Administered^http://snomed.info/sct/900000000000207008|

OBX|2|CNE|2620001000004108^Operative procedure ^http://snomed.info/sct/900000000000207008 ||26390003^Total colectomy^http://snomed.info/sct/900000000000207008|

OBX|3|CNE|399687005^Tumour site ^http://snomed.info/sct/900000000000207008 ||9040008^Ascending colon^http://snomed.info/sct/900000000000207008|

OBX|4|NM|200001000004104^Tumour dimension ^http://snomed.info/sct/900000000000207008 ||12|

OBX|5|CNE|788481000004105^Perforation^ ^http://snomed.info/sct/900000000000207008 ||47492008^Not identified^http://snomed.info/sct/900000000000207008|

OBX|6|CNE|1284862009^Histological tumour type ^http://snomed.info/sct/900000000000207008 ||1187332001^Adenocarcinoma^http://snomed.info/sct/900000000000207008|

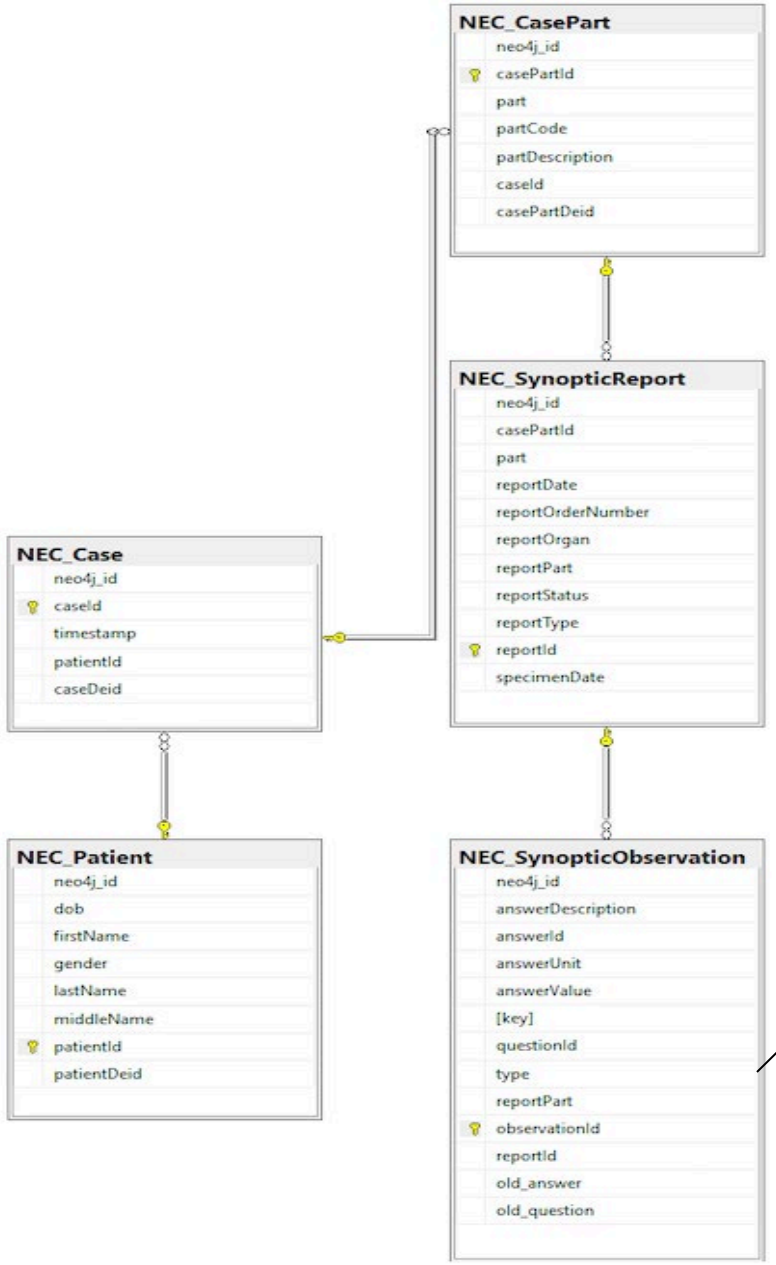
OBX|7|CWE|1285736001^Histological Tumour Grade ^http://snomed.info/sct/900000000000207008 |1155707008^High grade^http://snomed.info/sct/900000000000207008|

The Process

UNMC Tumor Biorepository Model

Synoptic Observations stored in RDBMS MS SQL structure

RDBMS allows easy to understand patient, report-level data



Graph allows for ECL-like query capability in runtime environment

SNOMED CT contained in MS SQL graph model

SCTID bound to graph

The Process

Samples of tractable questions:

- **Difference of tumor profile based on response to therapy prior to resection**
  - Final all breast cancer cases with synoptic data
  - Get two groups of cases:
    - Those with complete response to neoadjuvant therapy
    - Those will less than complete response to neoadjuvant therapy
  - Provide the histologic type, ER/PR/Her2 profiles of the tumors between both groups. Is there a difference in distribution?
- **Treatment approaches**
  - Find all ER+ breast cancer cases with:
    - tumor size <= 1mm
    - Number of lymph nodes involved < 3
  - Determine how many patients have received the following therapies:
    - Tomoxafin alone
    - Aromatase inhibitor therapy alone
    - CDK 4/6 inhibitor therapy with tomoxafin or aromatase inhibitor therapy

Step 1 – Find all breast cancer cases

166000100000 4100 |Histologic type of primary malignant neoplasm of breast (observable entity)|

SNOMED CT	Histology	Quantity
82711006	Infiltrating duct carcinoma (morphologic abnormality)	1099
89740008	Lobular carcinoma (morphologic abnormality)	204
49755003	Morphologically abnormal structure (morphologic abnormality)	82
1187425009	Carcinoma (morphologic abnormality)	66
72495009	Mucinous adenocarcinoma (morphologic abnormality)	22
1187332001	Adenocarcinoma (morphologic abnormality)	17
443933007	Ductal carcinoma in situ with microinvasion (morphologic abnormality)	13
4631006	Tubular adenocarcinoma (morphologic abnormality)	13
444057000	Infiltrating carcinoma with ductal and lobular features (morphologic abnormality)	11
128705006	Metaplastic carcinoma (morphologic abnormality)	7
22694002	Adenocarcinoma with apocrine metaplasia (morphologic abnormality)	6
703578005	Invasive micropapillary carcinoma of breast (morphologic abnormality)	4
703594003	Solid papillary carcinoma with invasion (morphologic abnormality)	4
703545003	Encapsulated papillary carcinoma (morphologic abnormality)	3
703596001	Tubulolobular carcinoma (morphologic abnormality)	2
373395001	Invasive ductal carcinoma with an extensive intraductal component (morphologic abnormality)	1

Step 2 – Stratify by response to neoadjuvant therapy

1255589007 | Presence of regression of primary malignant neoplasm of breast after neoadjuvant antineoplastic therapy (observable entity)|

SNOMED CT	Response	Quantity
1220561009	Not recorded (qualifier value)	2
2667000	Absent (qualifier value)	1
255545003	Definite (qualifier value)	1

Presence of regression of primary malignant neoplasm of breast after neoadjuvant antineoplastic therapy (observable entity)

SCTID: 1255589007

1255589007 | Presence of regression of primary malignant neoplasm of breast after neoadjuvant antineoplastic therapy (observable entity) |

en Presence of regression of primary malignant neoplasm of breast after neoadjuvant antineoplastic therapy (observable entity)

en Presence of regression of primary malignant neoplasm of breast after neoadjuvant antineoplastic therapy

Inheres in → Malignant neoplasm
Property → Presence (property)
Scale type → Ordinal value
Inherent location → Breast structure
Characterizes → Malignant proliferation of primary neoplasm
Characterizes → Regression of neoplasm
Precondition → Neoadjuvant antineoplastic therapy
Time aspect → Single point in time

Step 3 – Stratify by IHC Results

1234805007 |Presence of estrogen receptor in primary malignant neoplasm of breast by immunohistochemistry (observable entity)|

1234801003 |Presence of progesterone receptor in primary malignant neoplasm of breast by immunohistochemistry (observable entity)|

355000100004108 |Presence of receptor tyrosine-protein kinase erbB-2 in primary malignant neoplasm of breast by immunohistochemistry (observable entity)|

SNOMED CT	Estrogen Receptor	Progesterone Receptor	HER/Neu
Not recorded (qualifier value)	Positive	Positive	Negative
Not recorded (qualifier value)	Negative	Negative	Negative
Absent	Positive	Positive	Equivocal
Definite	Negative	Negative	Equivocal

Questions

University of Nebraska Medical Center

Nebraska Medicine