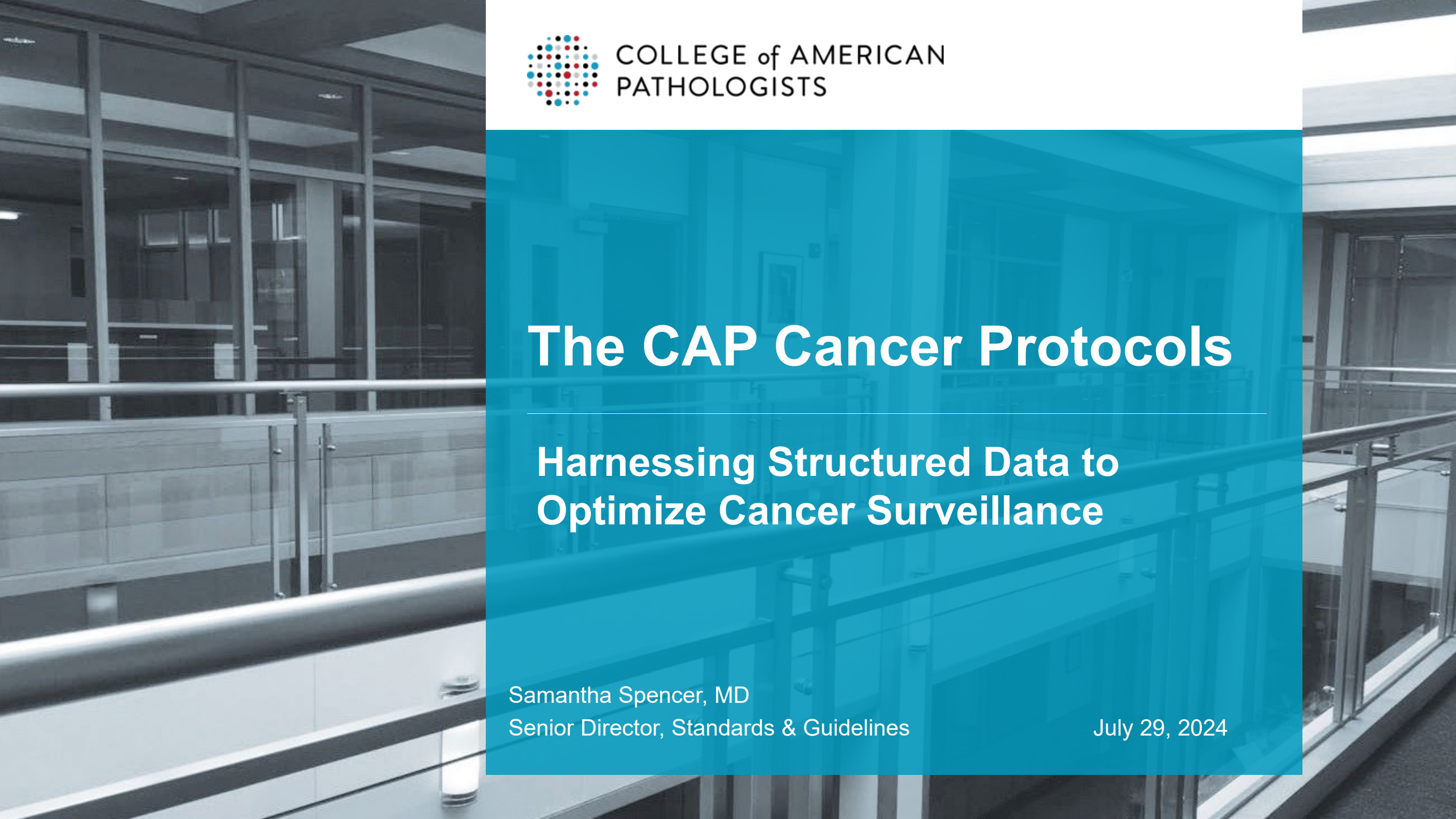


COLLEGE of AMERICAN PATHOLOGISTS

The CAP Cancer Protocols

Harnessing Structured Data to Optimize Cancer Surveillance

Samantha Spencer, MD
Senior Director, Standards & Guidelines

July 29, 2024

Agenda

- Background
- Successes
- Challenges and opportunities
- Future direction

What are the CAP Cancer Protocols?

COLLEGE of AMERICAN PATHOLOGISTS

Protocol for the Examination of Specimens From Patients With Primary Carcinoma of the Colon and Rectum

Version: Colon Rectum 4.0.1.0 **Protocol Posting Date:** June 2017
Includes pTNM requirements from the 8th Edition, AJCC Staging Manual

For accreditation purposes, this protocol should be used for the following procedures AND tumor types:

Procedure	Description
Colectomy	Includes specimens designated total, partial, or segmental resection
Rectal Resection	Includes specimens designated low anterior resection or abdominoperineal resection
Tumor Type	**Description**
Carcinoma	Invasive carcinomas including small cell and large cell (poorly differentiated) neuroendocrine carcinoma

This protocol is NOT required for accreditation purposes for the following:

Procedure
Excisional biopsy (polypectomy)
Local excision (transanal disk excision)
Primary resection specimen with no residual cancer (eg, following neoadjuvant therapy)
Cytologic specimens

The following tumor types should NOT be reported using this protocol:

Tumor Type
Well-differentiated neuroendocrine tumors (consider the Colorectal NET protocol)
Lymphoma (consider the Hodgkin or non-Hodgkin Lymphoma protocol)
Sarcoma (consider the Soft Tissue protocol)

Authors
Sanjay Kakar, MD*; Chanjuan Shi MD, PhD*; Mariana E. Berho, MD, PhD; David K. Driman, MBchB; Patrick Fitzgibbons, MD; Wendy L. Frankel, MD; Kalisha A. Hill, MD, MBA; John Jessup, MD; Alyssa M. Krasinskas, MD; Mary K Washington, MD, PhD

With guidance from the CAP Cancer and CAP Pathology Electronic Reporting Committees.

** Denotes primary author. All other contributing authors are listed alphabetically.*

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.

Version	Previous Version
)0.0)	2016 (v3.2.0.0)
.0.0.0)	2013 (v3.1.0.2)
7	
Version	Previous Version
)1.0)	2013 (v3.2.0.1)
.0.1.0)	
7	
Version	Previous Version
)0.1)	2017 (v4.0.0.0)
.0.0.1)	2016 (v3.4.0.0)
17#)	2013 (v3.3.0.0)
018	
Version	Previous Version
)1.0)	2017 (v4.0.0.0)
.0.1.0)	2016 (v3.4.0.0)
17#)	2013 (v3.3.0.0)
018	
Version	Previous Version
)0.1)	2017 (v4.0.0.0)
.0.0.1)	2016 (v3.6.0.0)
17#)	2016 (v3.5.0.0)
018	
Version	Previous Version
)0.0)	2016 (v3.2.0.0)
.0.0.0)	2013 (v3.1.1.2)
7	
Version	Previous Version
)0.0)	2013 (v3.1.0.2)
.0.0.0)	
7	
Version	Previous Version
)1.0)	2017 (v4.0.0.1)
.0.1.0)	2014 (v3.1.0.0)
17#)	
018	
Version	Previous Version
)0.0)	2011 (v3.1.0.0)
.0.0.0)	
7	

Search

idelines Publications

otocols Public Period

ent period for 14 draft new and rotocols ends June 10, 2019. s will be posted in August 2019

ls and submit your comments

CAP's vision is to improve patient outcomes through structured cancer pathology reporting solutions.

Vision

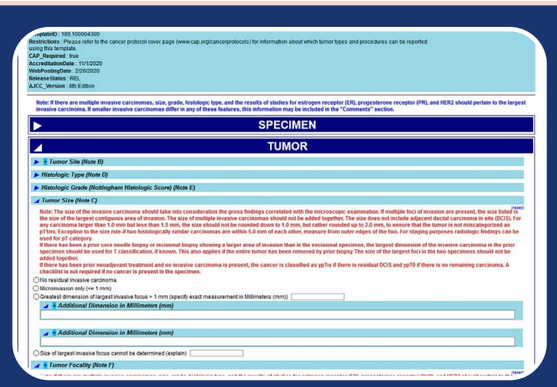
Improve patient outcomes by producing structured reporting solutions for pathology and cancer, primarily by leveraging industry leading standards that facilitate quality clinical practice and real-world applications of diagnostic data.

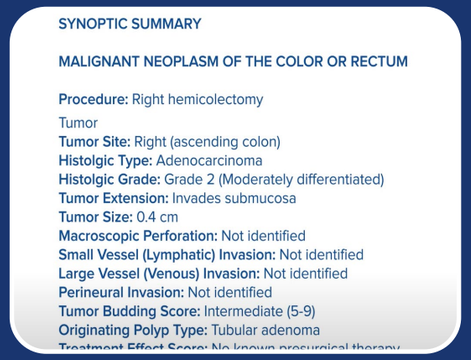
Value

The CAP leverages pathologist expertise and best practices to help clinicians make more informed, expedient, and cost-effective treatment decisions. This mitigates risks, supports pathologist workflow, aids laboratory compliance, ensures data fidelity for downstream use and public health, and most importantly, improves patient outcomes.

Who uses the CAP eCP, and why?

- Pathologists use the CAP electronic Cancer Protocols (eCP) to help them report on their definitive cancer resections, as well as some biopsies.
- Why use the eCP versus other cancer reporting mechanisms?





Data entry form integrates into pathologist workflow within AP-LIS system or middleware = **one-stop shopping**

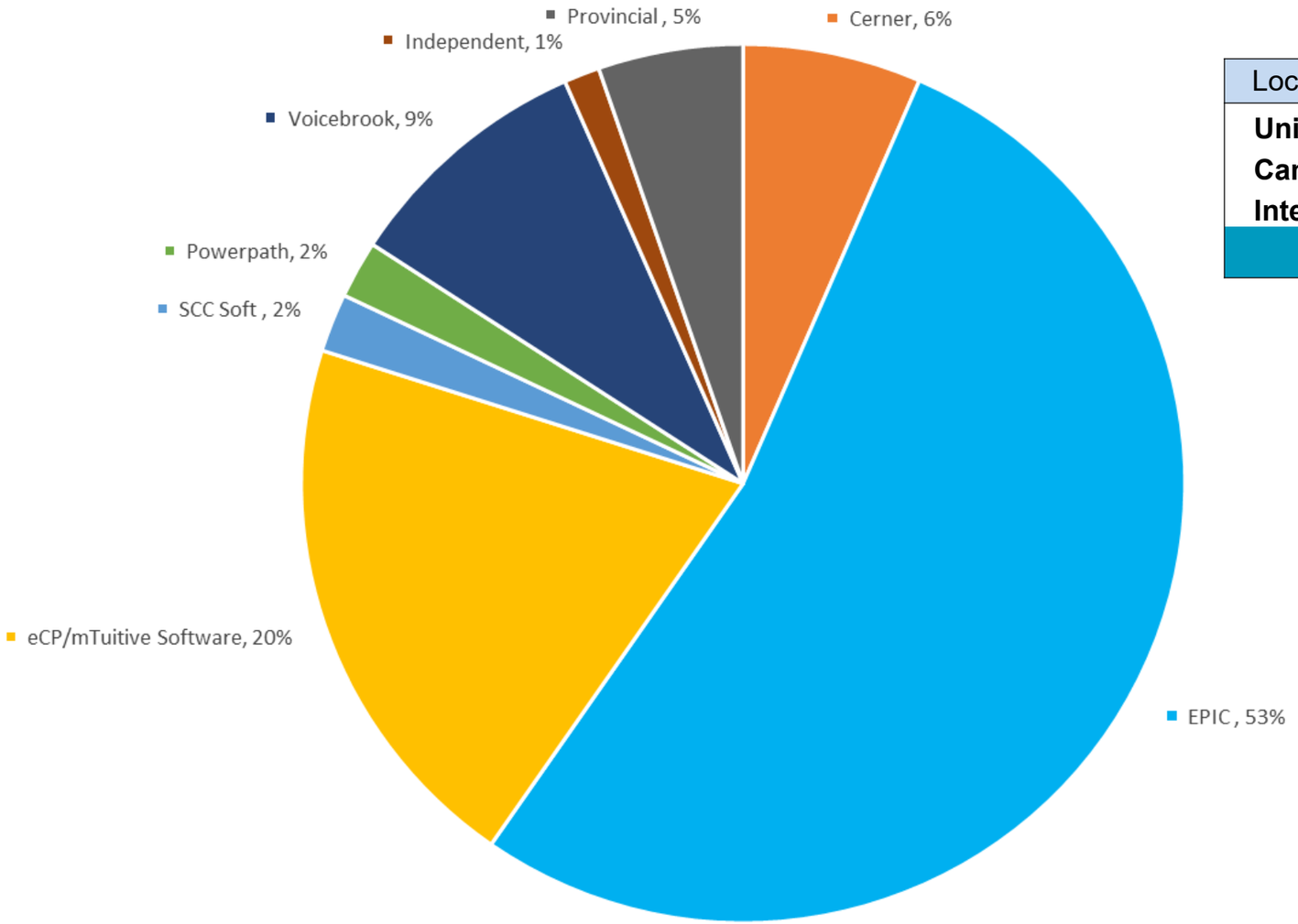
eCP acts as a **"smart" form**, with **auto-updates**, **CDS,** and a **completeness checker,** aiding in **accreditation compliance**

Goal of **synoptic report** is to make it easy for the clinician to find the **key pieces** of data needed for patient care

eCP generates structured data for **analytics & quality assurance**, helping improve processes and **patient care**

CAP eCP User Assessment July 2024

eCP User Laboratory Information Systems (LIS) and Middleware



Location	# of **Pathologists**
United States	**7456**
Canada	**920**
International	**39**
Total	**8415**

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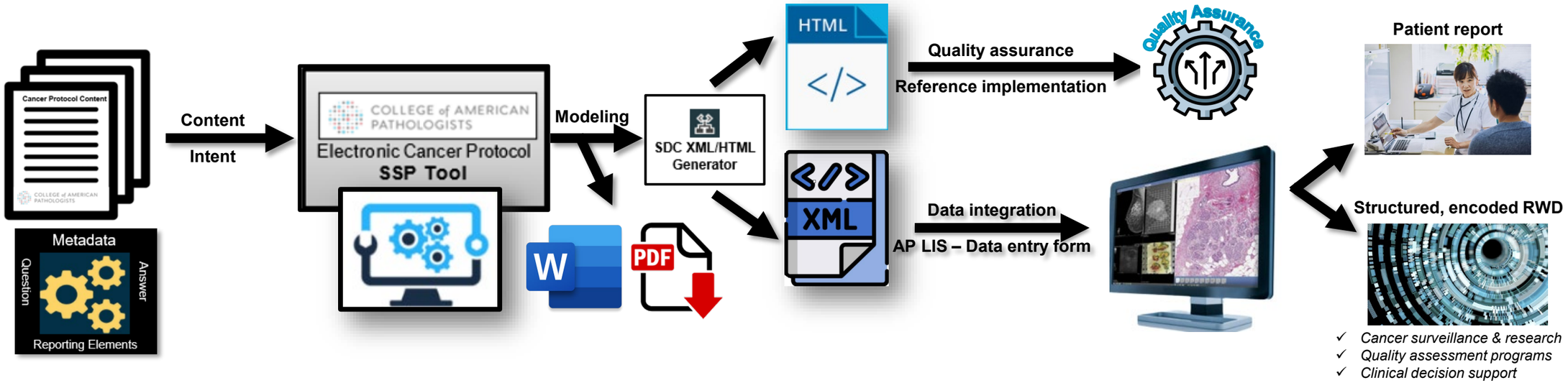
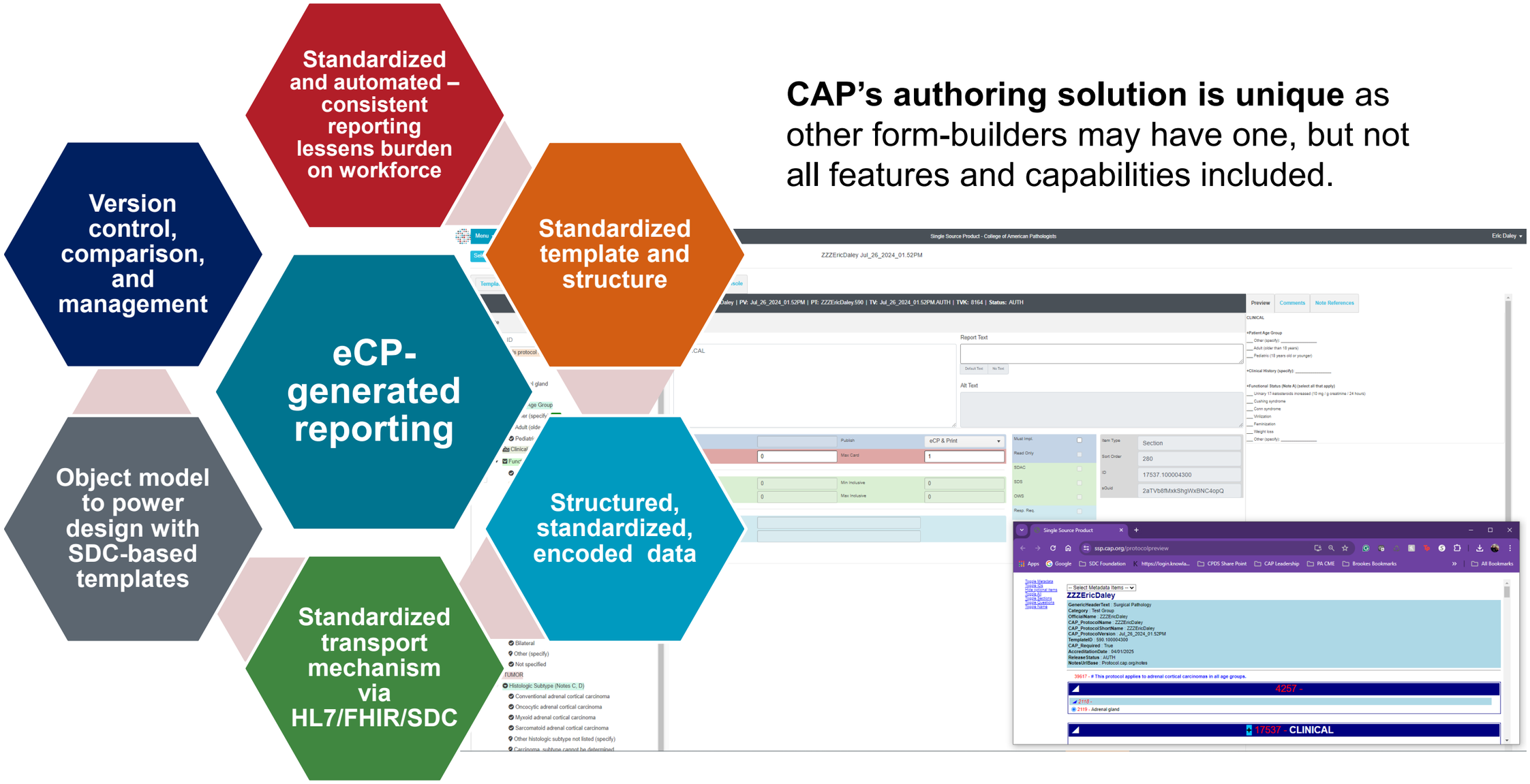
The CAP has a robust content generation program.



- CAP-developed web-based tool used to model and edit Cancer Protocols and other pathology data entry forms. Incorporates Structured Data Capture SDC Object Model.
- SDC is used to create standardized, interoperable question and answer sets (QAS) as structured data in data entry forms, as well as to map these data elements to SNOMED CT and ICD-O.
- PDF and Microsoft Word® documents are posted on www.cap.org/cancerprotocols.
- HTML is used for reference implementation/QA; XML files are integrated into vendor/LIS systems.
- CAP is engaging with organizations who are potentially interested in using this authoring tool.

A content management system now for the future.



CAP's authoring solution is unique as other form-builders may have one, but not all features and capabilities included.

Vendor implementation is a key to success.

Vendor engagement

- Clinical domain success working collaboratively and bidirectionally with vendors
- Monthly touch base meetings with yearly onsite, review implementation issues and feedback
- Opportunities for members to serve on advisory boards

Validation

- Vendor implementation validation sessions at least yearly, with ad hoc assessments as needed
- Self-audit vendor prework with live testing in vendor systems
- Scorecard report, pass-fail, work together on planning fixes and enhancements to support needs

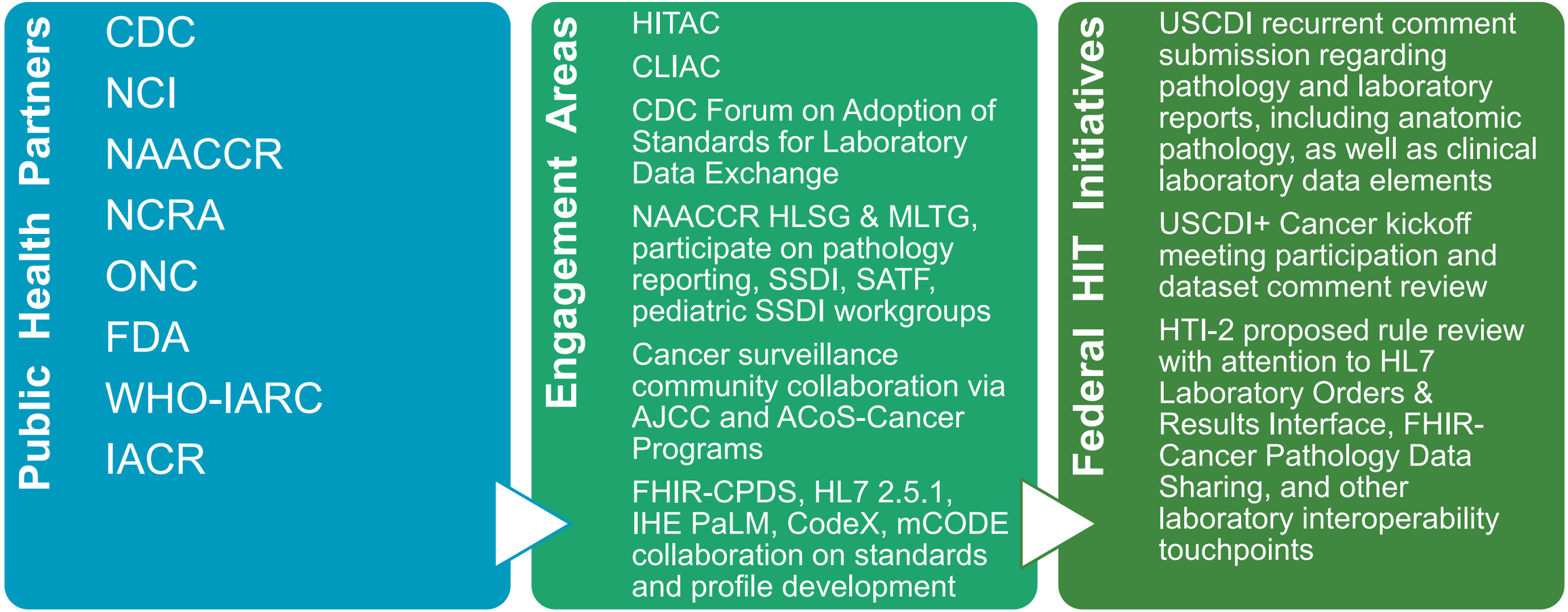
Data structure & transmission

- NAACCR Vol V onboarding, Epic and other vendors can support and reproducible
- Message validation
- IHE/HL7/FHIR Connectathons

Next steps

- Leverage interface engine to auto-validate vendor HL7 / FHIR messages
- Normalize standardized, structured data transmission to public health and downstream data uses
- Ensure public health entities can automatically receive and parse data without transformation

Engaging with public health and SDOs is core to achieving our goals and realizing our vision.



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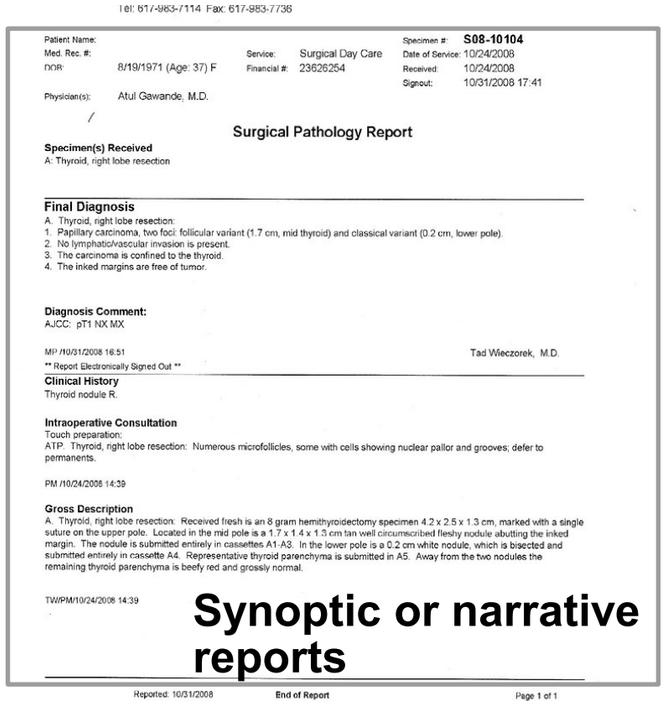
Much data in the clinical record is not structured or standardized.



Tel: 617-983-7114 Fax: 617-983-7736

Patient Name:
Med. Rec. #:
DOB: 8/19/1971 (Age: 37) F
Service: Surgical Day Care
Financial #: 23626254
Specimen #: S08-10104
Date of Service: 10/24/2008
Received: 10/24/2008
Signout: 10/31/2008 17:41
Physician(s): Atul Gawande, M.D.

Surgical Pathology Report

Specimen(s) Received
A: Thyroid, right lobe resection

Final Diagnosis
A. Thyroid, right lobe resection:
1. Papillary carcinoma, two foci: follicular variant (1.7 cm, mid thyroid) and classical variant (0.2 cm, lower pole).
2. No lymphatic/vascular invasion is present.
3. The carcinoma is confined to the thyroid.
4. The inked margins are free of tumor.

Diagnosis Comment:
AJCC: pT1 NX MX

MP /10/31/2008 16:51 Tad Wieczorek, M.D.
** Report Electronically Signed Out **

Clinical History
Thyroid nodule R.

Intraoperative Consultation
Touch preparation:
ATP. Thyroid, right lobe resection: Numerous microfollicles, some with cells showing nuclear pallor and grooves; defer to permanents.

PM /10/24/2008 14:39

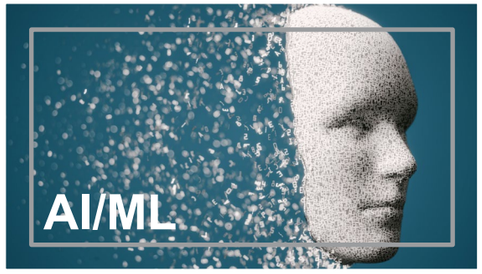
Gross Description
A. Thyroid, right lobe resection: Received fresh is an 8 gram hemithyroidectomy specimen 4.2 x 2.5 x 1.3 cm, marked with a single suture on the upper pole. Located in the mid pole is a 1.7 x 1.4 x 1.3 cm tan well circumscribed fleshy nodule abutting the inked margin. The nodule is submitted entirely in cassettes A1-A3. In the lower pole is a 0.2 cm white nodule, which is bisected and submitted entirely in cassette A4. Representative thyroid parenchyma is submitted in A5. Away from the two nodules the remaining thyroid parenchyma is beefy red and grossly normal.

TW/PM/10/24/2008 14:39

Reported: 10/31/2008 End of Report Page 1 of 1

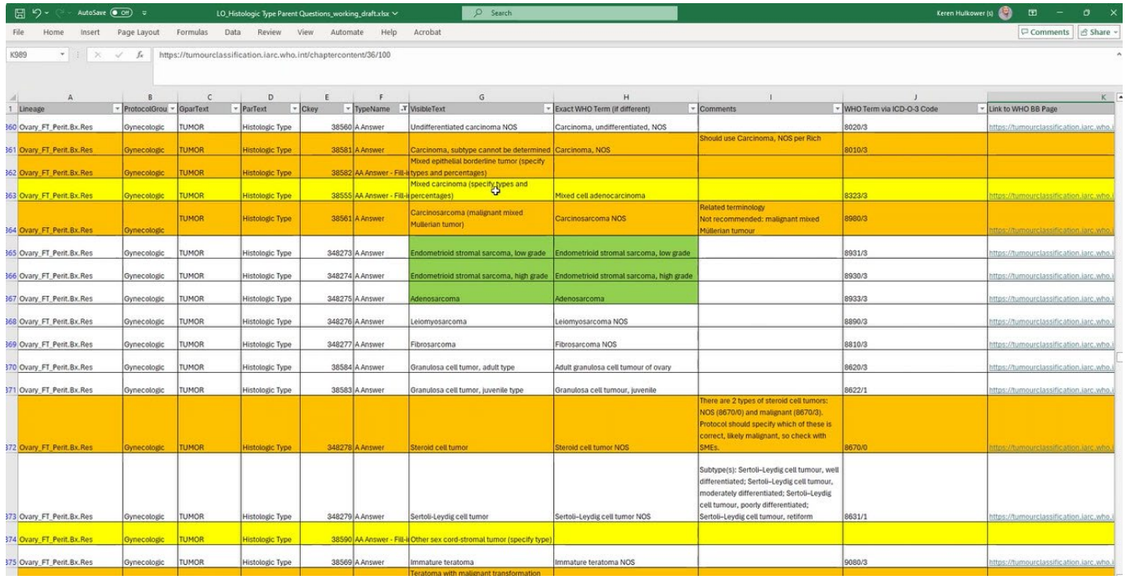
Synoptic or narrative reports

CAP eCP used by 50% pathologists



Standardized data encoding is still a challenge.

ICD-O and Cancer PathCHART activities



	A	B	C	D	E	F	G	H	I	J	K
1	Lineage	ProtocolGrou	QparText	ParText	Ckey	TypeName	VisibleText	Exact WHO Term (if different)	Comments	WHO Term via ICD-O-3 Code	Link to WHO BB Page
360	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	38560	A Answer	Undifferentiated carcinoma NOS	Carcinoma, undifferentiated, NOS		8020/3	https://tumourclassification.iarc.who.i
361	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	38581	A Answer	Carcinoma, subtype cannot be determined	Carcinoma, NOS	Should use Carcinoma, NOS per Rich	8010/3	
362	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	38582	AA Answer - Fill-i	Mixed epithelial borderline tumor (specify types and percentages)				
363	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	38555	AA Answer - Fill-i	Mixed carcinoma (specify types and percentages)	Mixed cell adenocarcinoma		8323/3	https://tumourclassification.iarc.who.i
364	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	38561	A Answer	Carcinosarcoma (malignant mixed Mullerian tumor)	Carcinosarcoma NOS	Related terminology Not recommended: malignant mixed Müllerian tumour	8980/3	https://tumourclassification.iarc.who.i
365	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	348273	A Answer	Endometrioid stromal sarcoma, low grade	Endometrioid stromal sarcoma, low grade		8931/3	https://tumourclassification.iarc.who.i
366	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	348274	A Answer	Endometrioid stromal sarcoma, high grade	Endometrioid stromal sarcoma, high grade		8930/3	https://tumourclassification.iarc.who.i
367	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	348275	A Answer	Adenosarcoma	Adenosarcoma		8933/3	https://tumourclassification.iarc.who.i
368	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	348276	A Answer	Leiomyosarcoma	Leiomyosarcoma NOS		8890/3	https://tumourclassification.iarc.who.i
369	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	348277	A Answer	Fibrosarcoma	Fibrosarcoma NOS		8810/3	https://tumourclassification.iarc.who.i
370	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	38584	A Answer	Granulosa cell tumor, adult type	Adult granulosa cell tumour of ovary		8620/3	https://tumourclassification.iarc.who.i
371	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	38583	A Answer	Granulosa cell tumor, juvenile type	Granulosa cell tumour, juvenile		8622/1	https://tumourclassification.iarc.who.i
372	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	348278	A Answer	Steroid cell tumor	Steroid cell tumor NOS	There are 2 types of steroid cell tumors: NOS (8670/0) and malignant (8670/3). Protocol should specify which of these is correct, likely malignant, so check with SMEs.	8670/0	https://tumourclassification.iarc.who.i
373	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	348279	A Answer	Sertoli-Leydig cell tumor	Sertoli-Leydig cell tumor NOS	Subtype(s): Sertoli-Leydig cell tumour, well differentiated; Sertoli-Leydig cell tumour, moderately differentiated; Sertoli-Leydig cell tumour, poorly differentiated; Sertoli–Leydig cell tumour, retiform	8631/1	https://tumourclassification.iarc.who.i
374	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	38590	AA Answer - Fill-i	Other sex cord-stromal tumor (specify type)				
375	Ovary_FT_Perit.Bx.Res	Gynecologic	TUMOR	Histologic Type	38569	A Answer	Immature teratoma	Immature teratoma NOS		9080/3	https://tumourclassification.iarc.who.i
							Teratoma with malignant transformation				

SNOMED CT mapping initiative with UNMC and CDC

	A	I	J	K	L	N	O	P	Q	R
1	Lineage	ParText	Ckey	TypeName	VisibleText		Question C-ke	Answer C-k	SCT Question	SCT Answer (if appropriate to be SCT)
55	Adrenal.Bx.Res	Tumor Weight	378866	AA Answer -	Other (specify)		40496	378866	371503009 |Neoplasm weight (observable entity)|	
56	Adrenal.Bx.Res	Tumor Weight	57476	AA Answer -	Cannot be determined		40496	57476	371503009 |Neoplasm weight (observable entity)|	1156316003 |Cannot be determined (qualifier value)|
57	Adrenal.Bx.Res	TUMOR	354224	QQQ Questic	Site(s) Involved by Direct Tumor Extension		354224		1155810009 |Anatomic location directly invaded by primary malignant neoplasm of adrenal gland (observable entity)|	
58	Adrenal.Bx.Res	Site(s) Involved by Di	50695	A Answer	Confined to adrenal cortex without invasion thro		354224	50695	1155810009 |Anatomic location directly invaded by primary malignant neoplasm of adrenal gland (observable entity)|	68594002 |Adrenal cortex structure (body structure)|
59	Adrenal.Bx.Res	Site(s) Involved by Di	39537	A Answer	Invades into or through the adrenal capsule		354224	39537	1155810009 |Anatomic location directly invaded by primary malignant neoplasm of adrenal gland (observable entity)|	84562008 |Structure of adrenal capsule (body structure)|
60	Adrenal.Bx.Res	Site(s) Involved by Di	56752	A Answer	Kidney		354224	56752	1155810009 |Anatomic location directly invaded by primary malignant neoplasm of adrenal gland (observable entity)|	64033007 |Kidney structure (body structure)|
61	Adrenal.Bx.Res	Site(s) Involved by Di	57748	A Answer	Pancreas		354224	57748	1155810009 |Anatomic location directly invaded by primary malignant neoplasm of adrenal gland (observable entity)|	15776009 |Pancreatic structure (body structure)|
62	Adrenal.Bx.Res	Site(s) Involved by Di	41409	A Answer	Liver		354224	41409	1155810009 |Anatomic location directly invaded by primary malignant neoplasm of adrenal gland (observable entity)|	10200004 |Liver structure (body structure)|
63	Adrenal.Bx.Res	Site(s) Involved by Di	42305	A Answer	Spleen		354224	42305	1155810009 |Anatomic location directly invaded by primary malignant neoplasm of adrenal gland (observable entity)|	78961009 |Splenic structure (body structure)|
64	Adrenal.Bx.Res	Site(s) Involved by Di	58229	A Answer	Diaphragm		354224	58229	1155810009 |Anatomic location directly invaded by primary malignant neoplasm of adrenal gland (observable entity)|	5798000 |Diaphragm structure (body structure)|
65	Adrenal.Bx.Res	Site(s) Involved by Di	46218	A Answer	Stomach		354224	46218	1155810009 |Anatomic location directly invaded by primary malignant neoplasm of adrenal gland (observable entity)|	69695003 |Stomach structure (body structure)|
66	Adrenal.Bx.Res	Site(s) Involved by Di	45594	AA Answer -	Other adjacent organs and structures (specify)		354224	45594	1155810009 |Anatomic location directly invaded by primary malignant neoplasm of adrenal gland (observable entity)|	
67	Adrenal.Bx.Res	Site(s) Involved by Di	51911	AA Answer -	Cannot be determined		354224	51911	1155810009 |Anatomic location directly invaded by primary malignant neoplasm of adrenal gland (observable entity)|	1156316003 |Cannot be determined (qualifier value)|
68	Adrenal.Bx.Res	Site(s) Involved by Di	44186	A Answer	Not applicable (no evidence of primary tumor)		354224		1155810009 |Anatomic location directly invaded by primary malignant neoplasm of adrenal gland (observable entity)|	385432009 |Not applicable (qualifier value)|

Mapping to standardized terminologies/ ontologies...

- Decreases total potential points of translation
- Fewer handoffs
- Less opportunity for misinterpretation, mismatch, error

  = **High fidelity data**

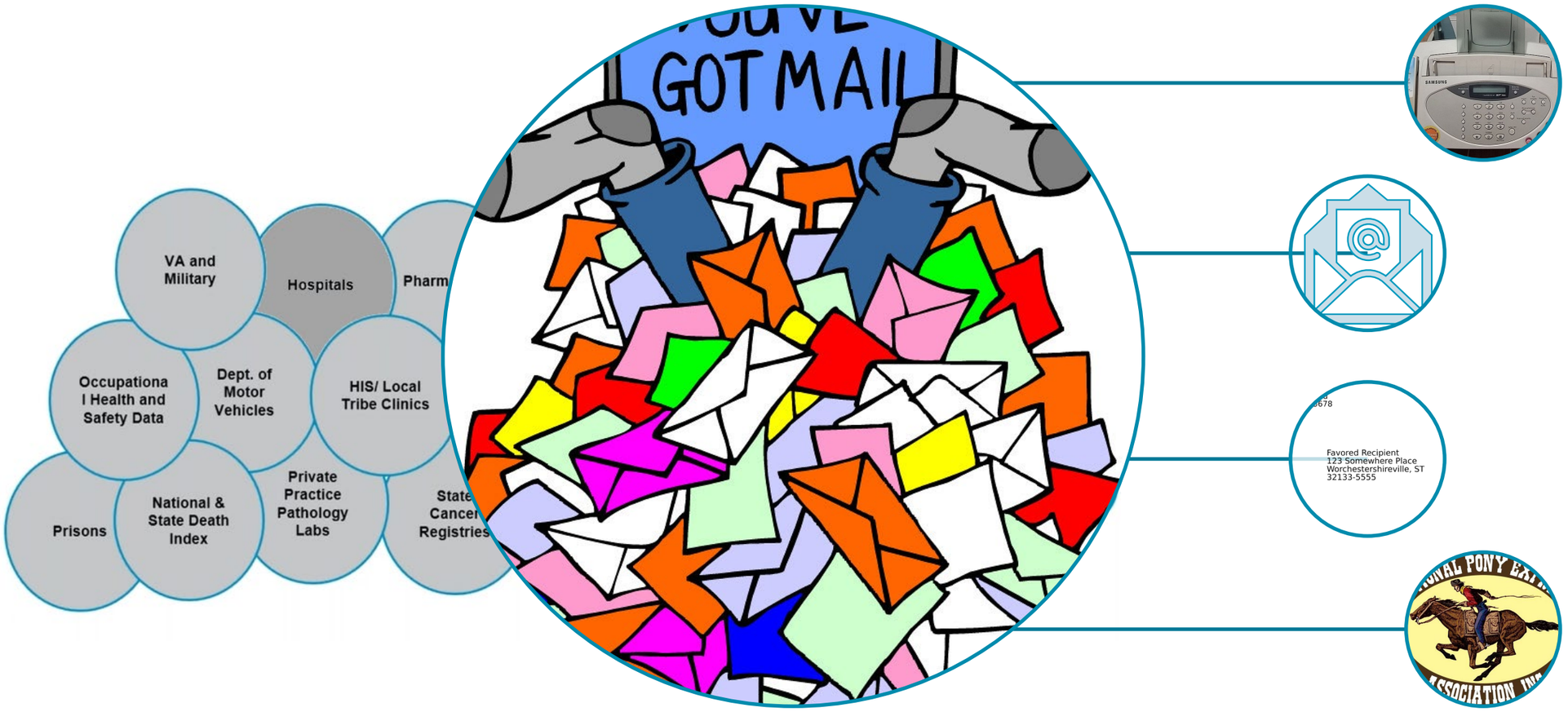
Why mapping vs. hard coding?

- UIDs needed for structured data independent of other release cycles and coding systems for usability and sustainability of reporting products in clinical domain
- Dedicated resources to ensuring keeping codes up to date and providing to our end users

If we have all this now, what challenges remain?

- Versioning
- Multiple sources vs. central hub
- Change management on national scale
- Strategic resourcing
- Carrot vs. stick

Data transmission to public health is not currently standardized.



Agenda

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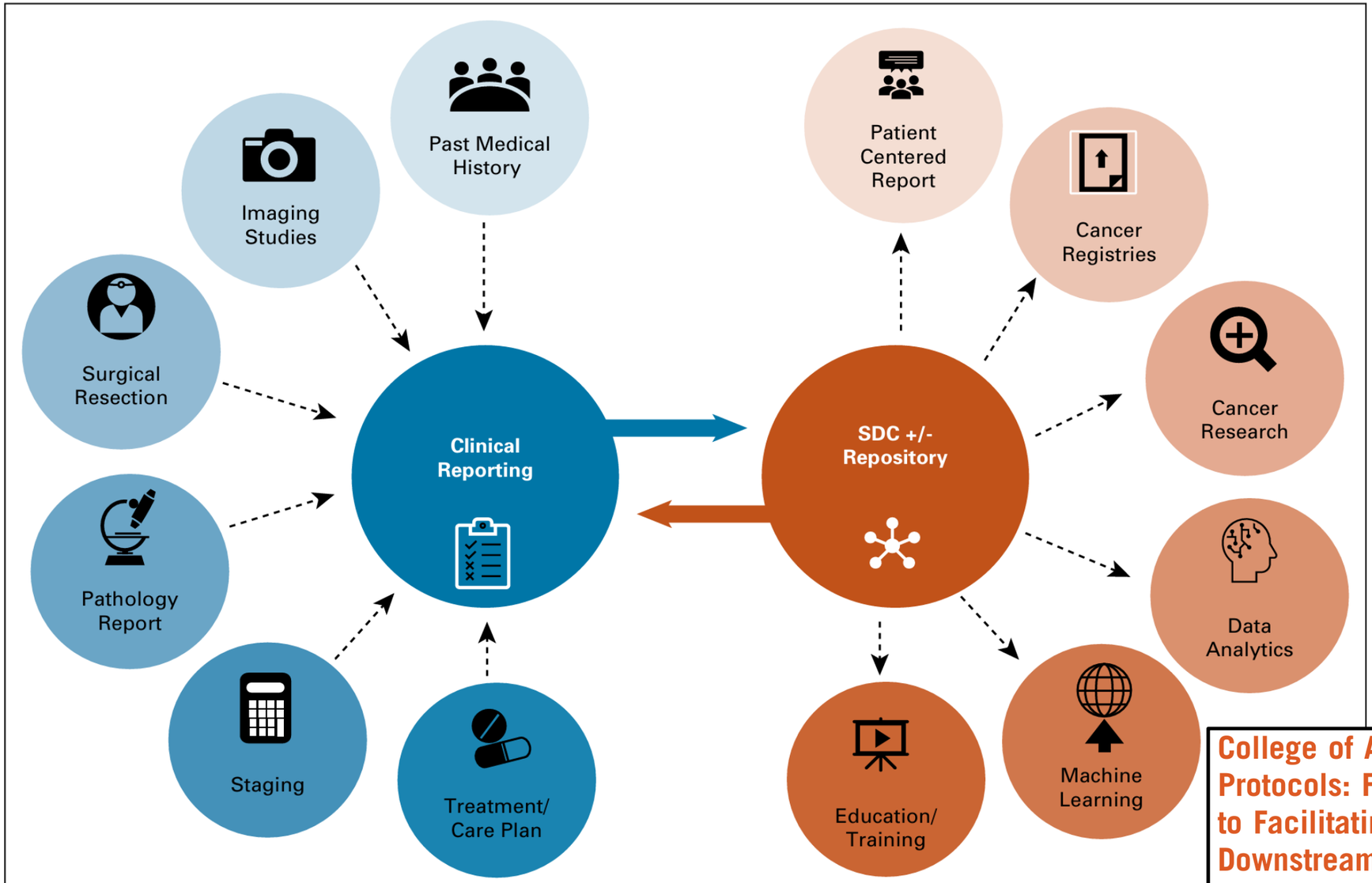
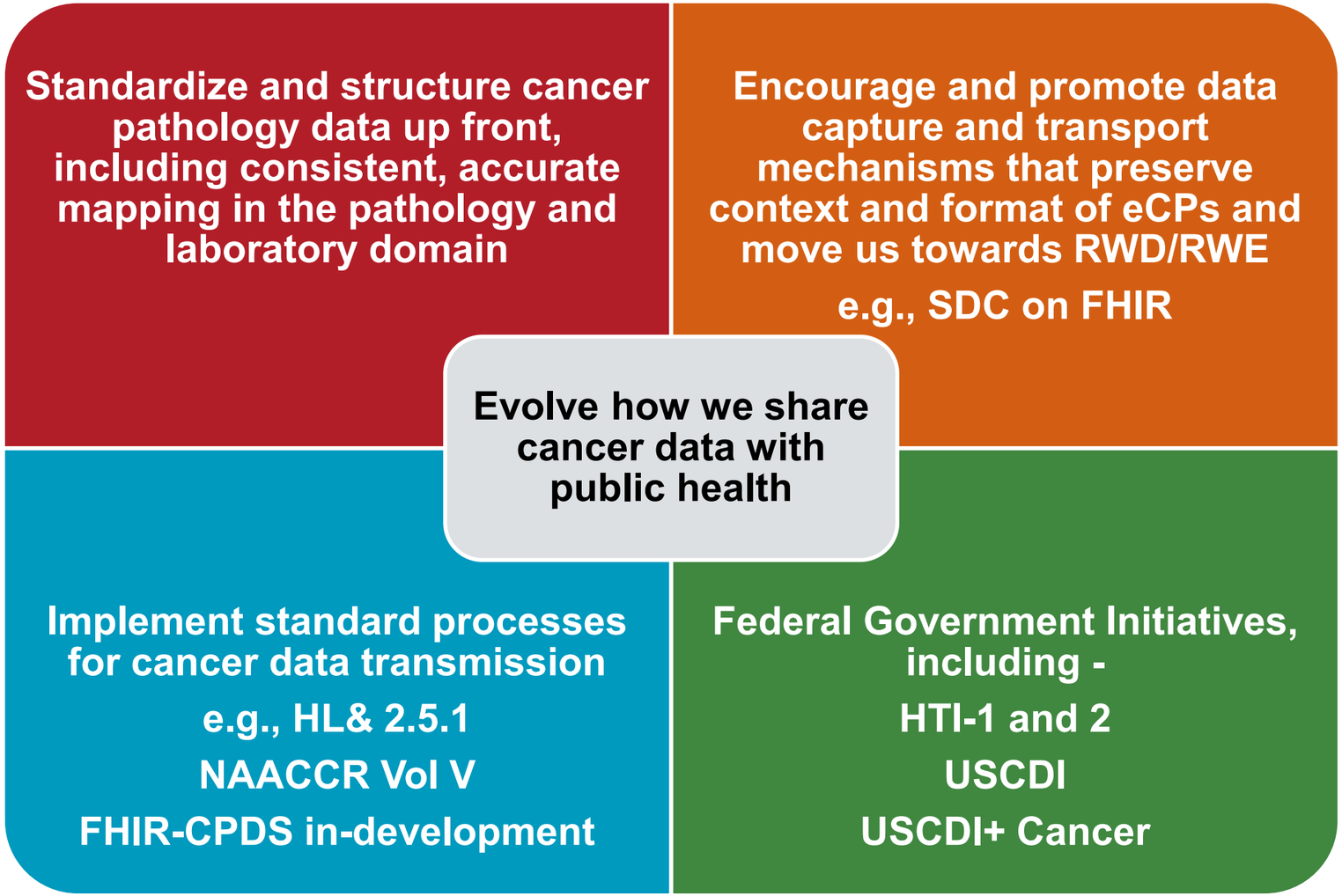
Vision of an interoperable future of cancer data exchange



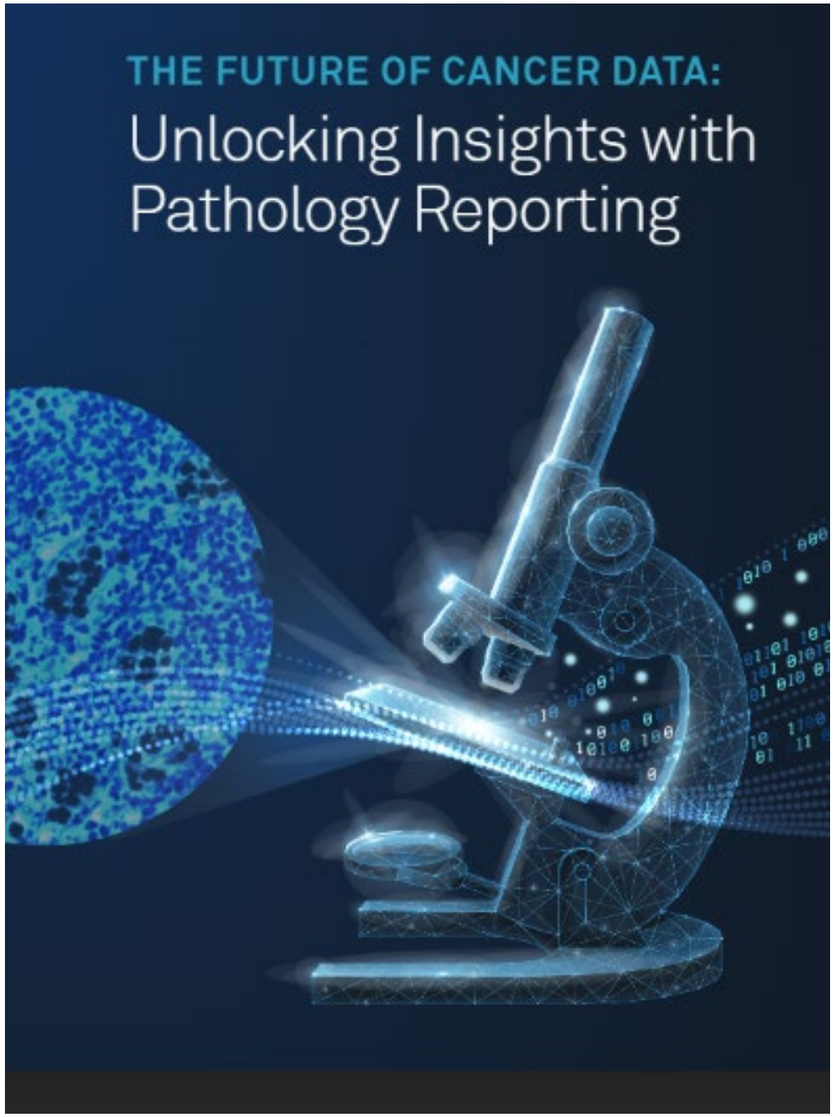
College of American Pathologists Cancer Protocols: From Optimizing Cancer Patient Care to Facilitating Interoperable Reporting and Downstream Data Use

Vanda F. Torous, MD[1]; Ross W. Simpson, MD[2]; Jyoti P. Balani, MD[3]; Alexander S. Baras, MD, PhD[4]; Michael A. Berman, MD[5]; George G. Birdsong, MD[6]; Giovanna A. Giannico, MD[7]; Gladell P. Paner, MD[8]; Jason R. Pettus, MD[9]; Zack Sessions, PharmD[10]; S. Joseph Sirintrapun, MD[11]; John R. Srigley, MD[12]; and Samantha Spencer, MD[10]

How do we get there?



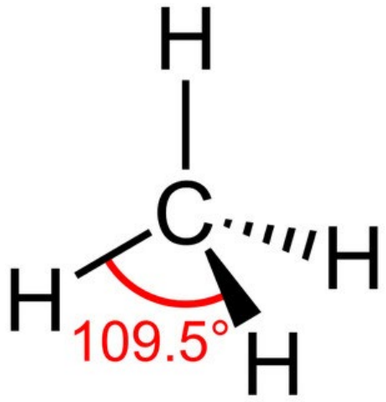
Education and training are essential to success.

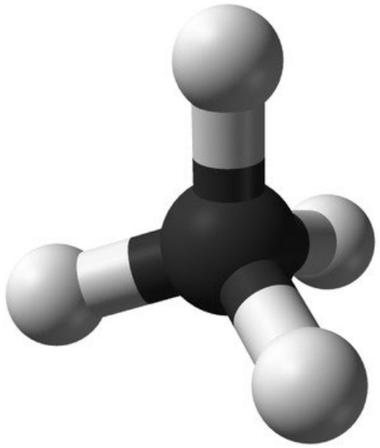


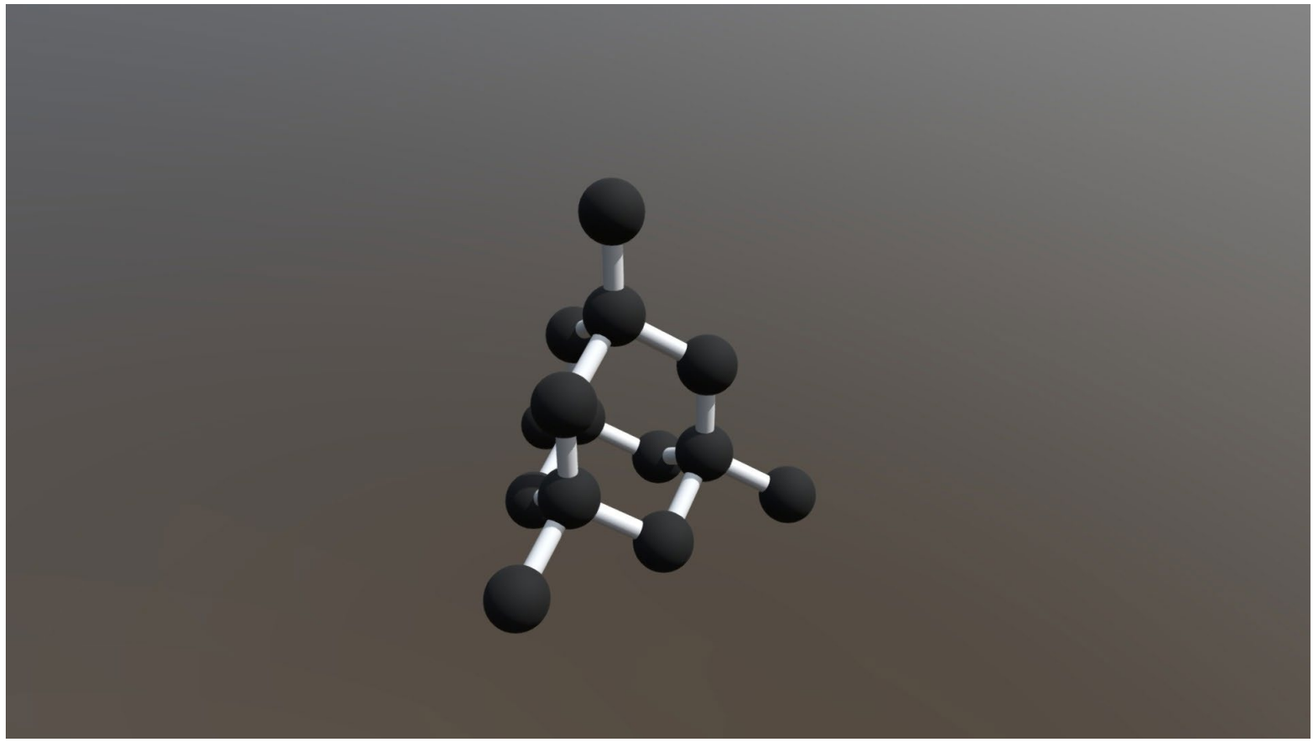
Cancer Data Champions Summit 10/6/2023

- Explored opportunities to shape the future of cancer pathology data use
- Identified new frontiers that will be shaped by using cancer pathology data
- Discovered how quality improvement programs can utilize synoptic reporting within and across laboratories
- Discussed how cancer pathology reporting to adds dimension to public health efforts
- Featured customer/user best practices
- 70+ attendees across pathology, oncology, surgery, public health, research, registrars, and industry
- Ongoing webinar series presents an opportunity to explore challenges and opportunities for interoperability across multiple healthcare disciplines and domains
- Next Cancer Data Summit @ CAP ’24 in Las Vegas 10/18/24

Carbon – the great connector







Key takeaways and needs for long-term success

Education & training

- Coordinated efforts across all healthcare domains
- Multidisciplinary meetings and webinar series like Cancer Data Champions, National Academies workshops
- Leverage ground-level training for future-facing mindset
- Open workgroup participation cross-functionally and to new in practice

Implementation focus

- Agreement on common goals and solutions
- Translate clinical successes into public health domain
- SDC everywhere via consistent use of standardized transmissions
- Vendor engagement promoting usability, functionality, and interoperability via LIS
- Public health and clinical organization partnerships, e.g., Cancer PathCHART, SNOMED CT

Support for adoption

- Public health, SDO, and clinical organization alignment for content and release schedules
- Standards framework support for laboratories and vendors
- We should reach for the stars, BUT we can't let the stars blind us to the path – the HOW matters to support successful coordination and execution
- Change management and support for this at a national level

CONNECTION - COMMON VISION - COLLABORATION - COORDINATION - CONTRIBUTION

COLLEGE of AMERICAN PATHOLOGISTS