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Cancer Laboratory Reporting to NY State Cancer Registry (NYSCR) using the Electronic Clinical Laboratory Reporting System (ECLRS)

For the NCI/SEER Site Visit, Sept 4, 2018

Outline

- Part 1: Background (Cancer Reporting Mandate) & Cancer-ECLRS Overview
- Part 2: Addressing Pathology Infrastructure Post Call Questions

Outline Part 1: Background and Overview

- Background: the Cancer Reporting Mandate
- Cancer Laboratory Recruitment and Goal
- Cancer-ECLRS: 10^{+} Yrs of Reporting: **Results**
- ECLRS and NYSCR “Reporting” Requirements
- The Term “Reporting Labs”-Caveat Emptor
- Routes of “Reporting” (AKA Ways of Transmission)
- Ensuring Standards-Based Interoperability & Quality
- Cancer-ECLRS Quality Assurance Processes
- Lab Reporting to Cancer-ECLRS: New “Use-Cases”
- Data Integration

Background: the Cancer Reporting Mandate

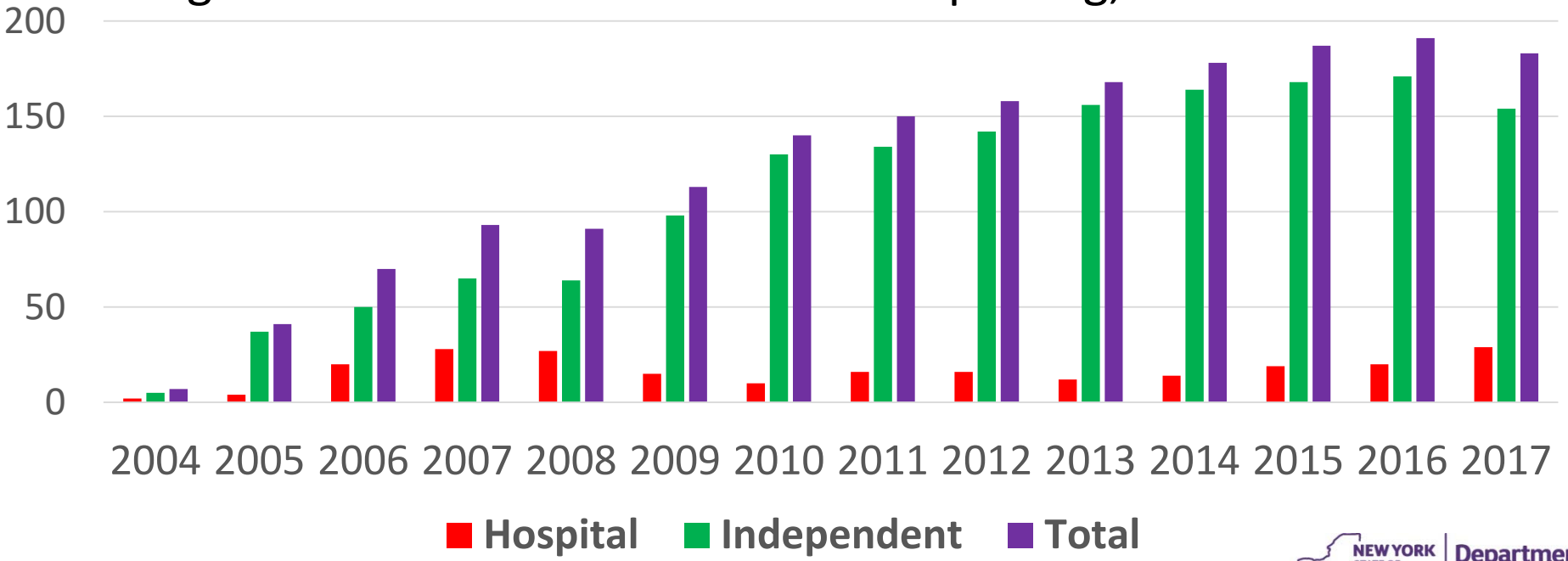
- 1940: Mandatory reporting of cancer to NYS, excluding New York City (NYC reporting mandate of 1973- reporting directly to NYS). (E.g., the NYS Public Health Law.)
- 1996 *electronic* reporting by hospitals to NYSCR
- 2001 the Cancer Program becomes more involved with the **ECLRS** Initiative.
- 2004 collaboration starts with the Clinical Laboratory Evaluation Program (**CLEP***), which is part of the Clinical Laboratory Reference System, part of the NYS DOH Wadsworth Center. *List of labs with 'cancer' testing permits.

Cancer Laboratory Recruitment and Goal

- Increase Compliance and Timeliness
- Facilitate better reporting of specific cancers (e.g., malignant melanomas of the skin, prostate cancers); usually diagnosed in a *non-hospital* setting, and therefore less likely to be reported. *Recently (2015) expanded to include on-boarding of facilities (hospital-based labs) with a high volume of childhood cancer cases.*
- Improve data quality as it relates to patients' demographic (race) or tumor (treatment) information. E.g., if the path lab's report is the only reporting source for a tumor, the NYSCR contacts the requesting provider to obtain additional info.

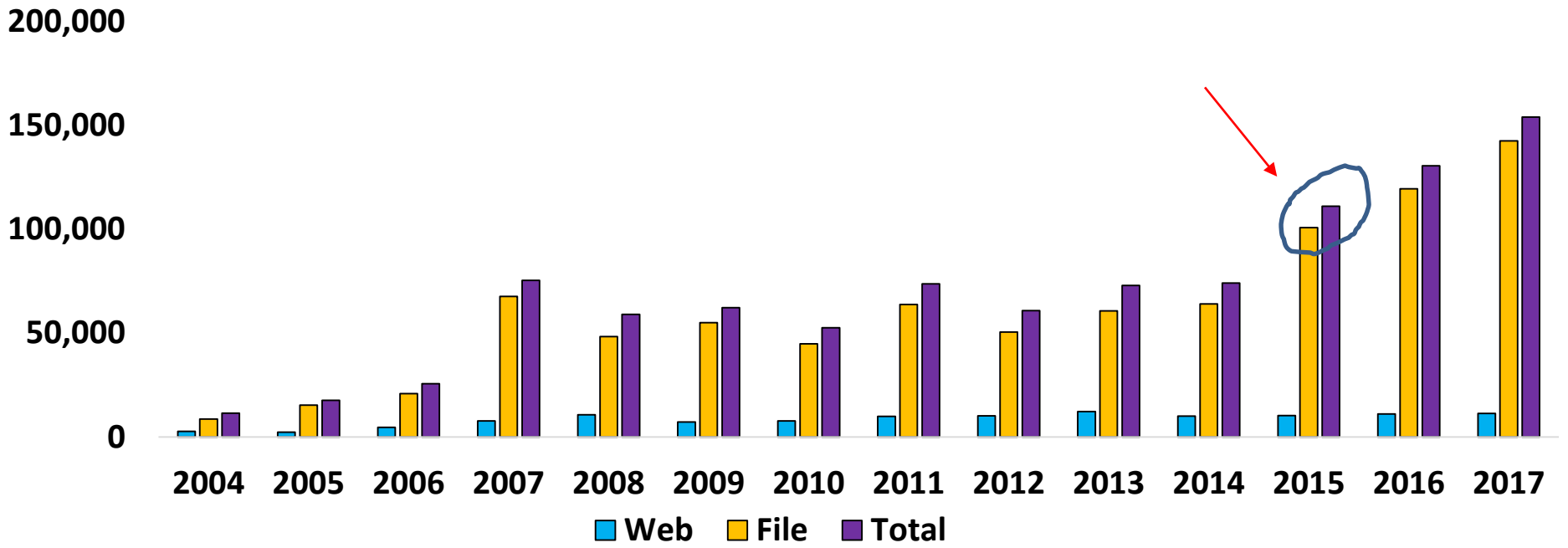
Cancer- ECLRS Ten+ Years of Reporting: Results

Figure 1: Number of Laboratories Reporting, 2004-2017



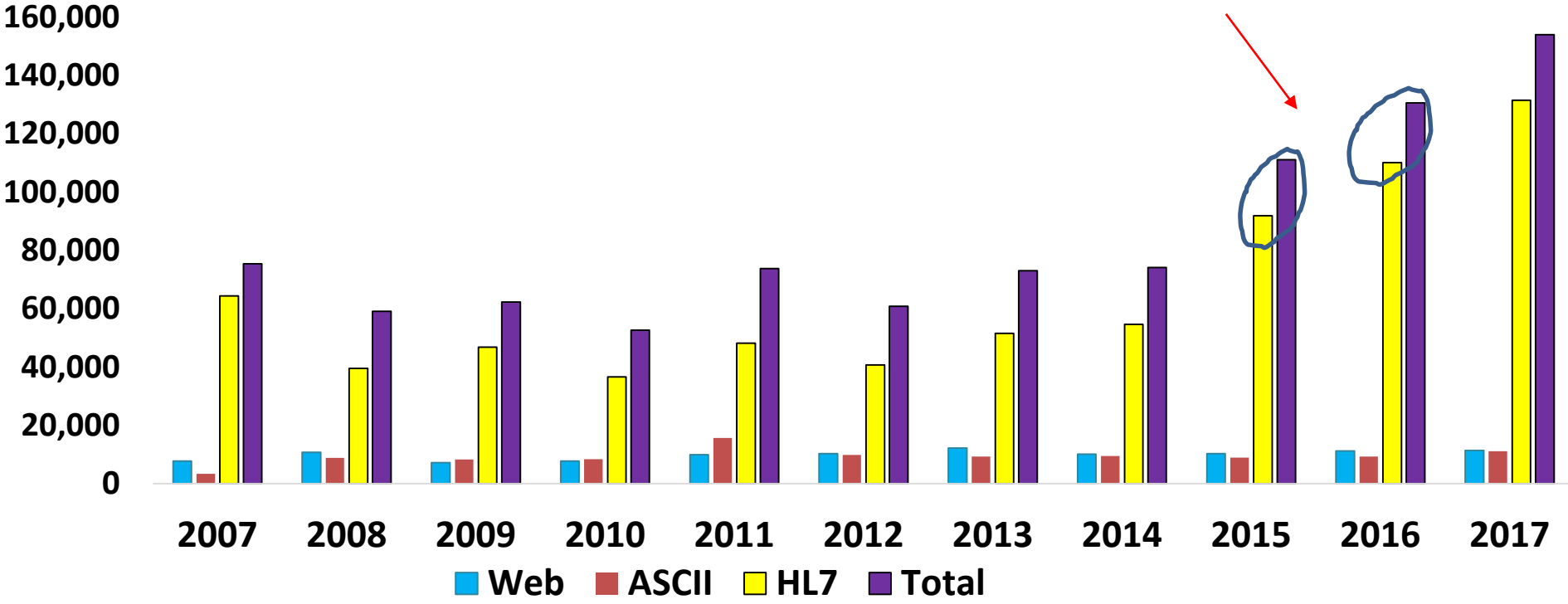
Cancer-ECLRS: Results Continued

Figure 2: Number of Pathology Reports Received, by General Submission Format, 2004-2017



Cancer ECLRS: Results Cont'd

Figure 3: Number of Pathology Reports Received, by *Specific* Submission Format, 2007-2017



ECLRS and NYSCR "Reporting" Requirements

- Completion of **H**ealth **C**ommerce **S**ystem Form for access to and reporting via HCS to Cancer-ECLRS.
- Format Selection: estimate the volume of reportable cancers – that determines the format in which the data will be submitted (e.g., an HL7 version 2.x message file, or manual web entry (HTML), or in rare cases, NAACCR ASCII.)
- Implementation of a case-finding 'filter' to select reportable, and weed out non-reportable records. The 'filter' is based on a list of codes and/or terms provided by NYSCR (e.g., SNOMED or ICD-10-CM codes), also vetted by CDC (NPCR).
- Creation of an LIS interface and production of a cancer-specific file, if volume is large.

“Reporting” Requirements Continued

- Successful completion of two **Certification Phases**: 1) The **Pre**-certification Phase (creating and sending of test files or practice of Web entry and submission into the Cancer-ECLRS **Test** environment); 2) NYSCR Cancer-ECLRS **Certification Phase** (sending of a minimum of 5 pathology (paper) reports (different types and/or sites) *and* successful transmission of these test reports in the chosen format.
  - An iterative process- there may be a need for several test files to be submitted before the laboratory is approved (certified by Cancer-ECLRS) for submitting to Cancer–ECLRS **Production** environment.

The Term “Reporting Labs*”- Caveat Emptor

- Clarification about the meaning of the term ‘reporting labs’:
- 1) Laboratories that ‘report’ may not be the ones that ‘transmit/send’ the data (pathology reports).
- 2) Laboratories that ‘transmit/send’ the data may not be the ones that ‘report’.
- 3) Some laboratories are ‘reporters’ and also ‘transmitters/senders’ of data (pathology reports).
- *In the NYS DOH ECLRS database the term ‘reporting lab’ is driven by/based on the Clinical Laboratory Improvement Amendments (CLIA) number.

Routes of "Reporting"- AKA Ways of Transmission*

- Transport (secure transfer protocol)- technology responsible for transmitting data between the lab and Cancer-ECLRS (e.g., UPHN Lite, (PHIN MS), SFTP, SSH).
- Labs submitting to Cancer-ECLRS may select to:
  - 1) Log on to the HCS and manually upload files, or
  - 2) Use UPHN Lite (NYS specific ftp software) for automated file uploads, or
  - 3) Manually do data entry (HTML/Web entry) into ECLRS via the HCS
  - *Test Environment & Production

E-Path Data “Routes”

- The E-path data ‘routes’ are characterized by the following:
  - ECLRS requirements
  - Laboratory’s volume of reportable cancer cases
  - A laboratory’s LIS (including legacy systems)
  - The level of technical know-how at the lab
  - Special requests (extracts by submission months, for a specific calendar year, e.g., January though June, 2017 message create date).

Ensuring Interoperability & Quality

- Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting, Version 2.2 or ver. 4.0, North American Association of Central Cancer Registries (NAACCR), Inc. , available from NAACCR's web site. (HL7 ver. 2.x based.)
- Cancer-ECLRS Implementation Manuals for file submission (HL7, ASCII) and/or for HTML/Web entry (manual entry using drop-down menu (ICD-O-3 based pick-lists).
- List of ICD-10-CM codes for case finding and/or ICD-O-3 list of reportable cancer terms.

HL7 Standard

HL7 2.x defines structure and content for health system messaging

NAACCR's Volume V

Standardizes cancer information messaging from the HL7 2.x and clarifies NAACCR usage

Local Implementation Guide

Defines and constrains NAACCR's Volume V to meet local/state cancer registry requirements

Cancer-ECLRS

Adapted from: HL7 2.5.1 Local Implementation Guide Condensed Template for Immunization Messaging Release 1.4 1/17/2013 (hl7guide-template-condensed-v1-4.doc); http://www.cdc.gov

Cancer-ECLRS Quality Assurance Processes

- Weekly review of volume, and timely submittal by labs.
- Bi-weekly review of Cancer-CLEP forms (provides the Registry an opportunity for “cross-validation”).
- Monthly review of labs with permits for ‘cancer testing’.
- Continuous QA feed-back to labs, a new QA Compliance Report, Cancer and facility-specific reports that document timeliness, number of path reports received, completeness of required or recommended fields, such as patient and provider information, incl. clinical history and final diagnosis.

Lab Reporting to Cancer-ECLRS: New "Use-Cases"

- The 10+ years of collaboration of NYS DOH NYSCR with ECLRS, and with CLEP, has enabled the NYSCR to capture specific cancer cases sooner and according to an established national standard.
- Rapid Case Ascertainment- Childhood Cancer Cases reported by Hospital-based Laboratories extracted monthly by ECLRS staff based on NYSCR specs.
- Cancer cases with specific cancer types selected for FDA-mandated, post-approval surveillance studies, extracted twice a month: e.g., Osteosarcoma Study, Medullary Thyroid Cancer Study.

Data Integration

- Currently cancer cases from labs reporting to Cancer-ECLRS for specific periods (monthly, or bi-weekly) and purposes (overall case finding, special studies) are extracted by ECLRS staff based on NYSCR requests
  - Standing/scheduled requests (monthly, bi-weekly)
  - Special requests (extracts by submission months, for a specific calendar year, e.g., January though June, 2017 message create date).
- Future Data Integration: Direct import (submission) via VPN from Cancer-ECLRS to NYSCR (SEER*DMS) based d-base.

Part 2

Addressing Pathology Infrastructure

Post Call Questions

Path Infrastructure Post Call Questions 1-3

- 1) How many labs use each “pathology route”?
- 2) If possible, provide list of labs using each route?
- 3) If possible, outline data transmission technologies for each route:
    - *a)* *Sender*- system at the lab that collects the data
    - *b)* *Transport* (secure transfer protocol) – technology responsible for transmitting data between lab and registry (e.g., PHIN MS, SFTP, SSH)
    - *c)* *Receiver*- System at the registry that receives the data (e.g. EMARC Plus)

Path Infrastructure Post Call Questions 4-5

- 4) For each pathology route, provide proportion of pathology reports that are ‘Reportable’ and ‘Non-reportable’
- 5) For each pathology route, provide proportion of histologically confirmed cases (CTCs) for which there is at least one pathology report

Answer to Question 1-Table 1a

"Pathology Routes" Used by *Transmitting* Laboratories: Term Path_route1a defined by 'Transmission' Method

Table 1a: Number of Laboratories, by Path_route1, Spec. Collection Year 2017

Path_route1a	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Manual upl-file	22	17.89	22	17.89
UPHN_Lite	32	26.02	54	43.90
Manual WEB/HMTL entry	69	56.10	123	100.00

Answer to Question 1Continued – Table 1a1

"Pathology Routes" Used by *Transmitting* Labs-
Number of Path Reports by Path_route1a:
Term Path_route1a defined by 'Transmission' Method

Table 1a*1*: Number of *Path Reports*, by Path_route1, for Dx Year 2017*

Path_route1	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Manual upl-file	29,167	22.37	29,167	22.37
UPHN_Lite	92,100	70.63	121,267	92.99
WEB/HMTL entry	9,136	7.01	130,403	100.00

* Dx Year= Specimen Collection Year

Answer to Question 1 Continued- Table 1b

"Pathology Routes" Used by *Transmitting* Labs:
Terms Path_route1b defined
by 'Transmission' Method & Data Format/Source Combination

Table 1b: Number of Path Labs, by Path_route1b, for 2017 Dx Year 2017*

Path_route1b	Frequency	Percent	Cumulative Frequency	Cumulative Percent
AIM$	16	13.01	16	13.01
ASC	3	2.44	19	15.45
HL7	35	28.46	54	43.90
WEB/HTML entry	69	56.10	123	100.00

* Dx Year= Specimen Collection Year

$ All are hospital-based labs using AIM's E-path products.

Answer to Question 1b Continued- Table 1b1

"Pathology Routes" Used by *Transmitting* Labs:
Number of Path Reports by Path_route1b: Term Path_route1b defined by 'Transmission' Method & Data Format/Source Combination

Table 1b*1*: Number of *Path Reports*, by Path_route1b, for Dx Year 2017

Path_route1b	Frequency	Percent	Cumulative Frequency	Cumulative Percent
AIM	74,549	57.17	74,549	57.17
ASC	7,189	5.51	81,738	62.68
HL7	39,529	30.31	121,267	92.99
WEB	9,136	7.01	130,403	100.00

Answer to Question 1 Cont'd- Table 1c

"Pathology Routes" Used by *Transmitting* Labs:

Terms: Path_route1a (transmission method); Data File Format (HL7 or ASCII, only)

Table 1c: Number of Path Reports, by Path_route1a & Data *File* Format, Dx Year 2017

	Path_route1	File_format		
		ASC	**HL7**	**Total**
Frequency	***Manual upl-file***	**7,189**	**21,978**	**29,167**
Percent		5.93	18.12	24.05
Row Pct		24.7	75.35	
Col Pct		100	19.27	
	UPHN_Lite	0	**92,100**	**92,100**
		0	75.95	75.95
		0	100	
		0	80.73	
	Total	**7,189**	**114,078**	**121,267**
		5.93	94.07	100
	Frequency Missing = 9,136 (Web/HTML)			

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Answers to Question 2 and 3

- Q2: List of labs using each ‘route’-*To be provided later*.
- Q3: List of transmission technologies for each “Pathology Route” by
    a) Sender System
    b) Transport
    c) Receiver
    - *To be provided later*.

Answer to Question 4

Table 1d: Proportion of Path Reports that are 'Reportable' and 'Non-reportable', by Path_route1a

	Path_route1a	Reportability				
		Yes	**No**	Auditable	Unk	Total
Frequency	**Manual upl-file**	14,545	12,880	1,716	26	29,167
Percent		11.15	9.88	1.32	0.02	22.37
Row Pct		**49.87**	**44.16**	5.88	0.09	
Col Pct		14.12	57.25	36.79	12.09	
	UPHN_Lite	80,628	8,751	2,558	163	92,100
		61.83	6.71	1.96	0.12	70.63
		87.54	**9.5**	2.78	0.18	
		78.26	38.9	54.85	75.81	
	WEB/HMTL entry	7,853	867	390	26	9136
		6.02	0.66	0.3	0.02	7.01
		85.96	**9.49**	4.27	0.28	
		7.62	3.85	8.36	12.09	
	Total	103,026	22,498	4,664	215	130,403
		79.01	17.25	3.58	0.16	100 %

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Answer to Question 4 Continued

Table 1e: Proportion of Path Reports that are 'Reportable' and 'Non-reportable', by Path_route1b

Path_route1b	Reportability				
	Yes	**No**	Auditable	Unk	**Total**
AIM	90.54	7.74	1.53	0.11	
ASC	88.3	11.25	0.4	0.04	
HL7	53.96	38.08	7.85	0.11	
WEB	85.96	9.49	4.27	0.28	
Total	79.01	17.25	3.58	0.16	100%

Answer to Question 5

Table 2a: Proportion of Histologically Confirmed cases (CTCs) for which there is at least one pathology report, by Path_route1a

	Path_route1a	Positive_histology		
		No	**Yes**	**Total**
Frequency	**Manual upl-file**	19,110	10,057	29167
Percent		14.65	7.71	22.37
Row Pct		65.52	**34.48**	
Col Pct		30.37	14.91	
	UPHN_Lite	39,147	52,953	92,100
		30.02	40.61	70.63
		42.5	**57.5**	
		62.2	78.48	
	WEB/HMTL entry	4,677	4459	9,136
		3.59	3.42	7.01
		51.19	**48.81**	
		7.43	6.61	
	Total	62,934	67,469	130,403
		48.26	51.74	100 %

Answer to Question 5

Table 2b: Proportion of Histologically Confirmed cases (CTCs) for which there is at least one pathology report, by Path_route1b

Path_route1b	Positive_histology		
	No	Yes	Total
AIM	37.04	62.96	
ASC	29.95	70.05	
HL7	72.07	27.93	
WEB	51.19	48.81	
Total	48.26	51.74	**100%**

Special Thanks To

Our colleagues at the NYSCR & NYSDOH:

Maria Schymura, Ph.D. (Director, Bureau of Cancer EPI),

Todd Szwetkowski, CTR

Jovan Ormsby, CTR

The Analysis and the Output Unit,

NYSCR Staff,

New York State Dept. of Health ECLRS Support Staff

Acknowledgement

This work was funded in part by grants from CDC and NCI/SEER awarded to the New York State Department of Health. The contents are solely the responsibility of the New York State Department of Health and do not necessarily represent the official views of the Centers for Disease Control and Prevention and/or NCI/SEER.