FCDS DATA VALIDATION AUDIT with E-PATH VERIFICATION

Diagnosis Year: 2013

Cancer Sites: Breast, Colon

Hospital Analytic Cases Only

Facilities: Appendix A

Preface

The Centers for Disease Control and Prevention National Program of Cancer Registries (CDC NPCR) requires that all states receiving funding under this program meet all NPCR Program Standards as defined in the NPCR Program Manual, v2.0 and the NPCR Program Standards 2012-2017. These standards are based on authority provided to the CDC under the Public Health Service Act (Title 42, Chapter 6A, Sub-Chapter II, Part M, § 280e) and subsequent amendments, and apply to all reportable cancers as defined in the Act and any amendments.

The Florida Department of Health (Florida DOH) also requires that Florida's statewide central cancer registry, the Florida Cancer Data System (FCDS), must meet all NPCR Program Standards as defined in the NPCR Program Manual, v2.0 and the NCPR Program Standards 2012-2017. FCDS operates the state cancer registry under contract with the Florida DOH.

The quality of data collected and reported by cancer registries depends upon the completeness of case identification, the completeness and accuracy of case reports, practices in place at the hospital and central cancer registry level, data quality monitoring including editing and record review, and adherence to national program standards (i.e. text documentation).

At least once every 5 years, a combination of re-casefinding (completeness) and re-abstracting (data validation) audits from a sampling of source documents are conducted for each hospital-based reporting facility in the state of Florida. Feedback is provided to individual reporting sources on data quality validation and completeness.

FCDS conducts annual re-casefinding audits via discharge diagnosis and procedures index submitted to the state Agency for Health Care Administration (AHCA) for 100% of in-patient encounters and 100% of ambulatory care patient encounters (hospital/non-hospital) occurring in the state of Florida each year. In addition FCDS conducts annual re-casefinding audits via patient/tumor linkage to external data files including Florida Vital Statistics (mortality), Florida Association of Pediatric Tumor Programs (FAPTP), and Breast and Cervical Cancer Early Detection Program (BCCEDP).

FCDS conducts annual re-abstracting (data validation) audits from a sampling of hospitals utilizing a sampling of source documents. The abstract, itself is a source document for the central cancer registry in that it is a primary source document for both patient and tumor consolidation, critical program components. Hence, inclusion of source documents for both the hospital and the central registry may reveal data quality issues or abstracting/reporting circumstance(s) for both the hospital-based reporting facility and the state central registry. Each may identify issues in need of attention at either or both the hospital-level or the central registry level in one or more key areas (i.e. data acquisition, data reliability, interpretation of rules/coding systems (including staging), patient/tumor consolidation, and overall data quality.

Audits may include manual/visual review of one or more source documents, data linkages of one or more electronic files from reporting facilities with the central cancer registry database with a cross-walk and/or comparison of output results.

This audit is designed to manually/visually review electronically matched e-pathology reports to hospital-submitted registry abstracts in combination with concentrated visual editing of analytic (diagnosed/treated at the audit facility) breast and colon cancer cases that were treated surgically at the facility to be audited. Text Documentation of specific data items has been an ongoing cancer reporting requirement for more than a decade with both requirements and expectations reinforced back to Florida registrars on a regular basis. The concentrated visual editing component of this audit is modeled after the NPCR Visual Editing Audit conducted early in 2013 for 2010 diagnoses, utilizes FCDS standard visual editing procedures routinely used to convey review findings across the state with similar selection and review criteria.

The audit methodology and design is intended to utilize existing and readily available source documents submitted by pathology labs (independent and hospital-based) and hospitals across the state of Florida to validate coded data and text from routinely reported original source abstracts and electronic surgical pathology reports routinely submitted by anatomic pathology labs across the state of Florida. Two levels of audit will be performed on each original record.

There will be no travel required and no need to gain access to any facility-based EMR System or multiple EMR Systems.

Hospitals will be required to complete a reconciliation phase when re-abstracted data (data abstracted during this audit) do not match the original data submitted from the facility base abstract or the electronic surgical pathology report(s).

Final results and recommendations to reporting facilities will include analysis of missing or incomplete pathology reports, missing or incomplete text documentation, accuracy of code selection (interpretation of coding rules and guidelines and proper code selection) for key data items, and other critical information identified as data quality concern(s).

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LIST OF ABBREVIATIONS

FCDS	Florida Cancer Data System
FCDS DAM	FCDS Data Acquisition Manual
FCDS IDEA	FCDS (Secure) Internet Date Entry and Abstracting Portal
DOH	Florida Department of Health
CDC	Centers for Disease Control and Prevention
NPCR	National Program of Cancer Registries
NAACCR	North American Association of Central Cancer Registries
E-Path	Electronic Anatomic Surgical Pathology Report
QC	Quality Control
EMR	Electronic Medical Records

1. BACKGROUND

A re-abstracting or data validation audit compares original abstract information and coded data to one or more source documents to validate the accuracy and "correctness" or validity of the data captured and coded when compared to original at-the-source documents (i.e. medical records or specific medical reports). The abstract is an original source document submitted by hospitals and ambulatory care centers to FCDS as part of routine cancer surveillance and state cancer reporting, and is utilized as such for case matching, un-duplication and both patient and tumor consolidation procedures. Completeness of text documentation, coding accuracy and validity of data are part of the triad of quality control measures for cancer registries (completeness, accuracy and timeliness). Completeness is a term used when assessing; completeness of case identification (casefinding), completeness of case reporting (abstract or other cancer report submission), and completeness of the text and/or data included in the abstract or cancer report. Accuracy is how correct or close to the original report (validity) the originally coded/abstracted data represent the case. Timeliness is the speed with which central registry data are collected, processed, analyzed, and made available for use.

The purposes of a re-abstracting audit are to:

- Identify discrepancies in the interpretation of abstracting and coding rules and instructions as well as abstracting tools available to registrars; or in the interpretation of information available in patient records.
- Identify missing information to determine if it was missed or truly unavailable.
- Estimate concurrence or agreement rates between the original data collector and the auditor—do the abstractor and the outside auditor both arrive at the same code?
- Identify any trends or patterns that may further characterize incorrect data. Thus providing potential opportunity for education and training, and to improve the interpretation/abstracting of the medical records among data collectors through educational opportunities based on the results of the audit.

A re-abstracting (data validation) audit serves as a surrogate measure of data accuracy for the central registry when the audit is conducted using a sample from a specific time period. Problems in the overall quality of central registry data can be identified and addressed immediately when abstracting issues are identified from the sample of cases.

Most re-abstracting (data validation) audits are not corrective or punitive in nature, but assess understanding of rules and guidelines for abstracting and provide opportunities for abstractor education and professional development.

Re-abstracting audits are designed to evaluate:

- Data quality, reliability and consistency - quality is loosely defined as "fitness for use"; reliability is a measure of assurance that two people will arrive at the same coding decision given the same information in the medical record; consistency involves the effort to monitor and minimize change over time in how data are interpreted.
- Registry performance - are the facilities that provide data to the central registry doing a good job of accurately representing the medical record using standard coding rules, form and format; and is the registry adhering to national and state abstracting and coding standards including the FCDS Text Documentation Requirements.

Re-abstracting audits also identify:

- Opportunities for quality improvement (e.g. can the central registry data base be made better through identification and correction of data issues or are the data inconsistencies minor resulting in minimal variation).
- Training issues (e.g. are cases being miscoded for particular reasons, such as lack of education).
- Strengths and deficiencies in reporting facilities in data quality and reliability (e.g. are there issues with specific types of cases being inaccurately or inconsistently coded and if so, is the problem facility-specific or statewide).

Reference: NPCR NETS Module 3 – Quality Control for Central Registries

2. OBJECTIVES

- Assess the validity and completeness of text, codes and text-supported codes provided to FCDS as a part of routine cancer case submission among selected Florida hospitals (data reliability, data quality, reliability).
- Assess the validity of data submitted when source abstract codes are compared to e-pathology coded data.

3. ELIGIBILITY

- Facilities will be selected according to 5-year selection criteria as well as stratified by 2013 reporting year caseload for each primary site to be audited (primary breast cancer/primary colon cancer).
- Facility may be selected for audit of only breast cases or only colon cases based on stratification criteria below.

Strata	Colon	Breast
1	10	16
2	21	47
3	39	104
4	39+	104+

- Case Selection will be based upon the following criteria:
  - Date of Diagnosis 01/01/2013-12/31/2013
  - Primary Site = C180-C189 (colon) or C500-C509 (breast)
  - Behavior = 2 (in-situ) or 3 (malignant)
  - Central Sequence = 00 (only 1 cancer ever reported)
  - ICD-O-3 Histology Not = 9590-9992 (no lymphoma, leukemia, or other hematopoietic malignancy)
  - Class of Case = 10, 11, 12, 13, 14, 20, 21, 22 (hospital analytic – diagnosed and/or treated at facility)
- Case Selection will stratified by 2013 reporting year caseload for primary breast cancer and primary colon cancer from calendar year 2013 diagnoses. A facility may be selected for only breast cancer audit or only colon cancer audit based upon the available cases meeting the strata described in the table above under Facility Selection.
- Pathology Selection will be based on any e-pathology report(s) with Date of Specimen within 30 days of the original Date of Diagnosis (plus or minus 30 days) as documented/coded on the original case abstract.

4. STUDY DESIGN

- Audit Process
  - Facility Selection – See Above Criteria
  - Case Selection – See Above Criteria
  - Pathology Selection - any available pathology report(s) with Date of Specimen within 30 days plus or minus of the original Date of Diagnosis as submitted with the original case abstract
  - Data Validation of Abstracted Case (completeness of text documentation and accuracy of coded data based on abstracted text – includes adherence to standard coding rules) – abstract text-to-code validation
  - Data Validation of E-Pathology Text (review of only 2013 e-pathology report(s) linked to Abstracted Case) (accuracy of abstract codes when compared to original source medical record)– e-path text-to-code validation
  - Reconciliation – All Data Discrepancies and all Audit Team Notes are Returned to Originating Hospital for Facility-Level Review, Resolution of Discrepancies, Clarification, or More Information (Additional Text). The facility will have all information available from the original abstract, re-abstracted text, and re-abstracted e-pathology data for any discrepancy. The facility will select and document which of the 3 codes is correct.
  - Manager Review of Data Validation Discrepancy Results, Facility Reconciliation, and Final Arbitration
  - Analysis of Audit Results in 2 Tiers
    - Abstract Text-to-Code Validation – original, 1st coded re-abstract, 1st coded e-path, reconciliation

  - E-Pathology Report Text-to-Code Validation – original, 1st coded re-abstract, 1st coded e-path, reconciliation
- Final Report and Recommendations

- **Data Items to be included in Data Validation of Abstracted Case** (completeness of text documentation and accuracy of coded data including adherence to standard coding rules) – abstract text-to-code validation

Item Name	Item #
Cancer Diagnosis Information	
Date of Diagnosis	390
Primary Site	400
Laterality	410
Histologic Type	522
Behavior	523
Grade	440
Stage of Disease Information	
CS Tumor Size	2800
CS Extension	2810
CS Lymph Nodes	2830
Number of Regional Nodes Positive	820
Number of Regional Lymph Nodes Examined	830
CS Metastasis at Diagnosis	2850
Derived SS 2000	3020
CS Site Specific Factors for Breast SSF1 – Estrogen Receptor Assay SSF2 – Progesterone Receptor Assay SSF15 – HER2 Result	 2880 2890 2869
Treatment Information	
Rx Summ – Surgery of Primary Site	1290
Scope of Regional Lymph Node Surgery	1292
Rx Summ – Radiation	1380
Radiation Modality	1570
Rx Summ – Chemotherapy	1390
Rx Summ – Hormone	1400
Rx Summ – BRM	1410
Rx Summ – Other	1420
Text Documentation	
All Text Fields Related to Above Data Items	2520-2690

- **Data Items to be included in Data Validation of E-Pathology Text** (accuracy)– e-path text-to-code validation

Item Name	Item #
Cancer Diagnosis Information	
Date of Diagnosis	390
Primary Site	400
Laterality	410
Histologic Type	522
Behavior	523
Grade	440

Stage of Disease Information	
CS Tumor Size (as available)	2800
CS Extension (as available)	2810
CS Lymph Nodes (as available)	2830
Number of Regional Nodes Positive (as available)	820
Number of Regional Lymph Nodes Examined (as available)	830

5. DATA COLLECTION PROCEDURES

- All data and reports to be used in this audit are readily available to FCDS Audit Team and are part of the greater Florida Cancer Data System. FCDS will build upon existing resources to build a custom audit data capture tool.
- Text from Abstracted Cases will be accessed by CTR Audit Team via secure https at FCDS IDEA.
- CTR Audit Team will code referenced data items using only the original source abstract text documentation.
- If text documentation is insufficient to code referenced data items, the data item will be coded "unknown"
- Text from E-pathology Cases will be accessed by CTR Audit Team via secure https at FCDS IDEA.
- CTR Audit Team will code referenced e-pathology data items using only the original source e-pathology report. However, they will have the FCDS Site Code Displayed so they know if the case is Colon or Breast.
- Cases will be alternately reviewed by a different member of the CTR Audit Team – so no single reviewer will be responsible for the review of both the original source abstract report and the original source e-pathology report.
- Comparison of Data and Statistical Reports will be produced using SAS or other statistical software.
- Disparate Data and Auditor Notes will be returned back to the originating facility via secure https at FCDS IDEA.
- Facility Responses to Disparate Data (case reconciliation) will be made via secure https at FCDS IDEA.
- FCDS Senior Quality Control Manager will serve as final arbiter when disparate data are noted. Final Coding Decisions will be documented in the FCDS audit record and updates made to source abstracts as needed.
- Auditor Instructions will be provided via FCDS Webcast and will be recorded and available for playback.
- Reconciliation Instructions will be provided via FCDS Webcast and will be recorded and available for playback.

6. DATA ANALYSIS

- Florida Standard Major/Minor Discrepancies for Audit

7. QUALITY CONTROL/QUALITY ASSURANCE

- The FCDS Data Validation Audit with E-Pathology Verification is a quality control/quality assurance activity involving multi-level independent and blinded reviews by FCDS Audit Team CTR staff, reconciliation at the originating institution, and final arbitration of disparate data by the FCDS Senior Manager of Quality Control.
- All national standard cancer surveillance coding rules and guidelines will be strictly followed in this audit.
- Original Reviews will be conducted by qualified CTRs with experience in data quality studies.
- Reconciliation Reviews will be conducted by staff at the original reporting institution, usually a CTR.

- Final Reviews will be conducted by the FCDS Senior Manager of Quality Control, also a CTR.
- Feedback on data quality and case completeness will be shared back to each originating institution as well as CTR Review Staff and will be presented in summary at the next FCDS Annual Conference.

8. REGULATORY REQUIREMENTS

8.1 FLORIDA STATUTE(S)

- Cancer reporting to FCDS is mandated by Florida statutes. All cancer cases seen in any health facility licensed under Florida Statute Section 395 or Section 408.07 must be reported to FCDS according to Florida Statutes Section 385.202. This includes all hospitals, ambulatory diagnostic and treatment centers, clinical laboratories and physicians' offices.

- State of Florida Cancer Reporting Statutes
  - *Florida Statute 381.0031*
  - *Florida Statute 385.202*
  - *Florida Statute 395*
  - *Florida Statute 405.01*
  - *Florida Statute 408.07*
  - *Florida Statute 483*
- State of Florida Administrative Code
  - *Rule 64D-3.004*
  - *Rule 64D-3.034*

8.2 Confidentiality

- According to Florida Statute 381, Public Health: General Provisions, "Information submitted in reports required by this section is confidential, exempt from the provisions of s.119.07 (1), and is to be made public only when necessary to public health. A report so submitted is not a violation of the confidential relationship between practitioner and patient." The Health Insurance Portability and Accountability Act of 1996 (HIPAA) became law April 14, 2001.

- HIPAA allows for the reporting of identifiable cancer data to public health entities. Because the Florida Cancer Data System falls under the definition of a public health entity, HIPAA allows your facility to continue to report data to us in compliance with state law. Written informed consent from each cancer patient reported to public health entities is not required under HIPAA; rather hospitals must simply document that reporting has occurred.

- FCDS continues to adhere to all Florida Statues and Department of Health guidelines, and follow strict security measures to assure patient and institutional confidentially.

- No institution or individual complying with Florida statutes 385.202, 405.01, 381.0031, and Florida State Administrative Code(may not have latest update) Rules 64D-3.004 and 64D3.034 shall be civilly or criminally liable for divulging information or providing materials to the statewide registry as required by the law.

9. REFERENCES

- 2013 FCDS Data Acquisition Manual (FCDS DAM) - *http://www.fcds.med.miami.edu/inc/DAM.shtml*
- 2007 Multiple Primary and Histology Coding Rules for Solid Tumors - *http://seer.cancer.gov/tools/mphrules*

- International Classification of Diseases for Oncology, 3rd Edition – World Health Organization, 2000
- Collaborative Stage Data Collection System, v02.04 - *http://www.cancerstaging.org/cstage*
- SEER*Rx - *http://seer.cancer.gov/tools/seerrx*
- National Program of Cancer Registries – NPCR Program Manual and NETS Training Module 3 - *http://www.cdc.gov/cancer/npcr*
- North American Association of Cancer Registries – Volume II: Data Standards and Data Dictionary – *http://naaccr.org*
- Florida Department of Health - *http://www.floridahealth.gov/diseases-and-conditions/cancer/cancer-registry/index.html*
- Florida Cancer Data System – *http://www.fcds.med.miami.edu*
- State of Florida Cancer Reporting Statutes
    - *Florida Statute 381.0031*
    - *Florida Statute 385.202*
    - *Florida Statute 395*
    - *Florida Statute 405.01*
    - *Florida Statute 408.07*
    - *Florida Statute 483*
- State of Florida Administrative Code
    - *Rule 64D-3.004*
    - *Rule 64D-3.034*

APPENDICES

- *Appendix A – Facilities to Be Audited for 2013 Diagnosis Year*
- *Appendix B – FCDS Data Validation and Visual Editing – Guidelines and Instructions*
- *Appendix C – Data Items to Be Validated – Abstracted Cases*
- *Appendix D – Data Items to Be Validated – E-Pathology Reports*
- *Appendix E – Sample Facility Audit Information Sheet*
- *Appendix F – Sample Reports*
- *Appendix G – Audit Timeline*

Appendix A

Facilities and Number of Cases to Be Audited for 2013 Diagnosis Year

	Colon Strata	Facility	Analytic Colon Cases		# Cases Selected
1	1	1405	3		3
2	1	1602	3		3
3	1	4546	10		9
4	1	5606	4		4
5	1	6446	8		8
6	1	7407	6		6
7	2	1649	17		9
8	2	1687	15		9
9	2	2736	19		9
10	2	3938	17		9
11	2	3988	21		9
12	2	7405	13		9
13	3	1601	36		9
14	3	2372	31		9
15	3	2738	30		9
16	3	4690	30		9
17	3	6600	23		9
18	3	7446	24		9
19	4	1170	71		9
20	4	2358	41		9
21	4	3906	54		9
22	4	6074	42		9
23	4	6278	54		9
24	4	6846	43		9
	TOTAL Colon		**615**		**195**

	Breast Strata	Facility	Analytic Breast Cases		# Cases Selected
1	1	1508	7		7
2	1	1676	5		5
3	1	4170	16		9
4	1	5446	3		3
5	1	6707	1		1
6	1	7407	10		9
7	2	1687	38		9
8	2	1800	28		9
9	2	3906	42		9
10	2	5110	19		9
11	2	5200	36		9
12	2	7446	45		9
13	3	1510	60		9
14	3	2348	62		9
15	3	2700	69		9
16	3	2736	76		9
17	3	4105	80		9
18	3	6347	61		9
19	4	1170	226		24
20	4	2376	411		43
21	4	2738	160		18
22	4	6068	118		13
23	4	6251	164		18
24	4	6936	219		24
	TOTAL Breast		**1956**		**282**
			TOTAL		**477**

Appendix B

FCDS Data Validation and Visual Editing – Standard Text Documentation Guidelines and Instructions

Text documentation is an essential component of a complete cancer registry abstract and is heavily utilized in quality control activities to validate data on a routine basis, for FCDS, NPCR, or external Audit, and for special studies. **Text documentation is required to justify coded values** and to supplement information not transmitted with coded values. **FCDS recommends that abstractors print and post this document for easy reference.** Adequate text is a data quality indicator and is a major part of QC. Below is a list of FCDS Required Data Items that carry an additional requirement of complete and accurate text documentation. See Table on Following Page for Text and Date Examples for each Text Area.

DATA ITEMS REQUIRING COMPLETE TEXT DOCUMENTATION *Data Items to be Included in Data Validation Audit (Appendix C and D)	
Date of DX *	RX Summ – Surg Prim Site *
Seq No	RX Summ – Scope Reg LN Surgery *
Sex	RX Summ – Surg Oth Reg/Distant
Primary Site *	RX Date – Surgery
Sub Site *	RX Summ – Radiation *
Laterality *	Rad Rx Modality *
Histologic Type *	RX Date – Radiation
Behavior Code *	RX Summ – Chemo *
Grade *	RX Date – Chemo
	RX Summ – Hormone *
CS Tumor Size *	RX Date – Hormone
CS Ext *	RX Summ – BRM/Immunotherapy *
CS Tumor Ext/Eval	RX Date – BRM/Immunotherapy
Regional Nodes Positive *	RX Summ – Transplant/Endocrine
Regional Nodes Examined *	RX Date – Transplant/Endocrine
CS LN *	RX Summ – Other *
CS LN Eval	RX Date - Other
CS Mets *	
CS Mets Eval	Any Unusual Case Characteristics
Breast CS SSFs 1 (ER), 2 (PR), 15 (HER2) *	Any Pertinent Patient/Family History

***See Appendix C and Appendix D for selected data items to be included in this data validation audit.**

Data items were selected to reflect case completeness and overall data quality and to reinforce basic rules and instruction regarding abstracting cancer cases in the state of Florida. At this time, only these data items are included in routine visual editing. Other data items may be added to the list based on availability, changes to data collection rules, or other reason.

What Should Be Included in Text Fields:

- Date(s) – include date(s) references – this allows the reviewer to determine event chronology
- Date(s) – note when date(s) are estimated [i.e. Date of DX 3/15/2014 (est.)]
- Location – include facility/physician/other location where the event occurred (test/study/treatment/other)
- Description – include description of the event (test/study/treatment/other) – include positive/negative results
- Details – include as much detail as possible – document treatment plan even if treatment is initiated as planned
- Include "relevant-to-this-person/cancer" information only – edit your text documentation
- DO NOT REPEAT INFORMATION from section to section
- DO USE Standard Abbreviations
- DO NOT USE non-standard or stylistic shorthand
- Enter "N/A" or "not available" when no information is available related to any specific text area.

Discrepancy: A discrepancy is defined as the quality or state of being discrepant, i.e., disagreeing, being at variance. A discrepancy arises when text documentation is absent or when a more appropriate code should have been selected for a data item based on the submitted text. Documented text must support coded values for all items noted in this appendix.

Quality Control of Audit Staff: In order to evaluate the quality of FCDS Audit Staff, the automated software program, allows FCDS to monitor the quality of visual editors. In addition, FCDS conducts routine (monthly/quarterly/annual) recoding audits on each FCDS auditor. All audit staff are CTRs in good standing.

Quality Improvement – Closing the Loop with Education and Training: In order to be consistent in the determination of what constitutes a discrepancy, the Florida Cancer Data System will conduct periodic quality control teleconferences, webcasts, or in-person meetings to discuss visual editing issues.

Educational workshops for cancer registry personnel are conducted by both the regional and central registry. In addition, both state and local cancer registrars associations hold educational workshops. It is important for cancer registry personnel to make every effort to attend these workshops.

SAMPLE TEXT DOCUMENTATION BY TEXT FIELD

Text Data Item Name **NAACCR Item #** **Field Length**	**Text Documentation Source and Item Description** *FCDS Required Text Documentation* **Example:**
Text - Physical Exam H&P NAACCR Item #2520 Field Length = 1000	Enter text information from history and physical exams. *History and physical examination findings that relate to family history or personal history of cancer diagnosis, physical findings on examination, type and duration of symptoms, reason for admission.* **Example: Hx RCC Rt Kidney – Dx 9/2011 in Georgia. Adm c/o fever and night sweats. Adm for w/u and found to have enlarged axillary nodes which on biopsy revealed diffuse B-cell lymphoma.**
Text - X-rays/Scans NAACCR Item #2530 Field Length = 1000	Enter text information from diagnostic imaging reports, including x-rays, CT, MRI, and PET scans, ultrasound and other imaging studies. *Date, facility where procedure was performed, type of procedure, detailed findings (primary site, size of tumor, location of tumor, nodes, metastatic sites), clinical assessment, positive/negative results* **Example: 4/12/15 (Breast Center xyz) Mammo - Rt Breast w/1.5cm mass at 12:00 o'clock**
Text - Scopes NAACCR Item #2540 Field Length = 1000	Enter text information from diagnostic endoscopic examinations. *Date of Procedure, facility where procedure was performed, type of procedure, detailed findings (primary site, extent of tumor spread, satellite lesions), clinical assessment, positive/ negative results* **Example: 4/12/15 (Endoscopy Ctr xyz) EGD: gastric mucosa w/ evidence of large tumor occupying half of the stomach. Numerous satellite tumors seen on opposite wall of the stomach**
Text - Lab Tests NAACCR Item #2550 Field Length = 1000	Enter text information from diagnostic/prognostic laboratory tests (not cytology or histopathology). **Text for Collaborative Stage Site Specific Factor or SSF documentation.** *Date(s) of Test(s), facility where test was performed, type of test(s), test results (value and assessment)* **Example: 4/12/15 (Hosp xyz) ER +, PR - , HER2 neg by IHC method, PSA 5.3 (elevated)**

Text Data Item Name **NAACCR Item #** **Field Length**	**Text Documentation Source and Item Description** *FCDS Required Text Documentation* **Example:**
Text - Operative Report NAACCR Item #2560 Field Length = 1000	Enter text information from surgical operative reports (not diagnostic needle, incisional biopsy). Include observations at surgery, tumor size, and extent of involvement of primary or metastatic sites. *Date of procedure, facility where procedure was performed, type of surgical procedure, detailed surgical findings, documentation of residual tumor, evidence of invasion of surrounding areas* **Example: 4/12/15 (Hosp xyz) right colon resection - Pt was found to have extensive disease in the pelvis (carcinomatosis) and resection was aborted, no biopsies were taken, no specimen obtained.**
DX Text - Pathology NAACCR Item #2570 Field Length = 1000	Enter text information from cytology and histopathology reports. *Date of specimen/resection, facility where specimen examined, pathology accession #, type of specimen, final diagnosis, comments, addenda, supplemental information, histology, behavior, size of tumor, tumor extension, lymph nodes (removed/biopsied), margins, some special histo studies* **Example: 2/5/15 (Hosp xyz) – Path Acc # - Rectum: Final Dx: adenoca, 2.5cm, ext. to pericolic fat. 1/22 lymph nodes + , margins neg, S100 stain is positive (melanoma, sarcoma), pT3N1Mx**
DX Text - Staging NAACCR Item #2600 Field Length = 1000	Enter **Details of Collaborative Stage** and other stage information not already entered in other text areas. Include specific information on Tumor Size, Extension of Primary Tumor, Metastatic Sites, etc. *Organs involved by direct extension, size of tumor, status of margins, sites of distant metastasis, special consideration for staging, overall stage, etc*. **Text for SSF documentation if not under Labs**. **Example: 2/15/15 - T2aN1a per path, distant mets in lungs, ER/PR neg, HER2 neg by IHC method**
RX Text - Surgery NAACCR Item #2610 Field Length = 1000	Enter text describing the surgical procedure(s) performed as part of 1st course treatment. *Treatment plan, date surgery performed, type of procedure, facility where surgery was performed* **Example: 2/15/15 (Hosp xyz) - rt breast mrm w/ax ln dissection**
RX Text **Radiation (Beam)** NAACCR Item #2620 Field Length = 1000	Enter information regarding the treatment of the tumor being reported with radiation. *Treatment Plan (if no treatment given), date treatment initiated/completed, facility where treatment administered, type of radiation, dose (if known)* **Example: 2/15/15-3/15/15 (Hosp xyz) – 45 Gy orthovoltage with 10 Gy boost to tumor bed**
RX Text **Radiation (Other)** NAACCR Item #2630 Field Length = 1000	Enter information regarding the treatment of the tumor being reported with radiation. *Treatment Plan (if no treatment given), date treatment initiated/completed, facility where treatment was administered, type of radiation, dose (if known),* **Example: 2/15/15 (Hosp xyz) - radioactive seed implant, radioisotopes (I-131)**
RX Text - Chemo NAACCR Item #2640 Field Length = 1000	Enter information regarding the treatment of the tumor being reported with chemotherapy. *Date treatment initiated, facility/physician office where administered/prescribed, name of agent(s)/protocol, dose/cycle (if known), treatment plan(if known)* **Example: 2/15/15 (Dr Smith) – Start 6 cycles R-CHOP – standard dose 2-week intervals**

Text Data Item Name **NAACCR Item #** **Field Length**	**Text Documentation Source and Item Description** *FCDS Required Text Documentation* **Example:**
RX Text - Hormone NAACCR Item #2650 Field Length = 1000	Enter information regarding the treatment of the tumor being reported with hormone. *date treatment initiated, facility/physician office where administered/prescribed, name of hormone/anti-hormone agent or procedure, dose (if known), Treatment Plan* **Example: 2/15/15 (Dr Jones) - tamoxifen (dose/duration not stated) or bilateral orchiectomy**
RX Text - BRM NAACCR Item #2660 Field Length = 1000	Enter information regarding the treatment of the tumor being reported with biological response modifiers or immunotherapy. *date treatment initiated, facility/physician office where administered/prescribed, name of BRM or immunotherapy agent or procedure, dose (if known), Treatment Plan,* **Example: 2/15/15 (Hosp xyz) - interferon or BCG (dose/duration not stated)**
RX Text - Other NAACCR Item #2670 Field Length = 1000	Enter information regarding treatment that cannot be defined as surgery, radiation, or systemic therapy. *Date treatment planned/initiated, name of other therapy, agent or procedure, dose (if known), facility where performed* **Example: 2/15/15 (Hosp xyz) - blinded clinical trial or hyperthermia (may include study number)**
Text - Remarks NAACCR Item #2680 Field Length = 1000	Document information not provided in any other text field or overflow from text fields. Document personal history of carcinogenic exposure (arsenic, drinking water, uranium, asbestos), other **Example: 40 year h/o of working in ship building and construction w/ lots of asbestos exposure**

Appendix C

Data Items to be Validated – Abstract Review

Data Items to be Validated Abstract Review	
Date of DX	RX Summ – Surg Prim Site
Primary Site	RX Summ – Scope Reg LN Surgery
Laterality	RX Summ – Radiation
Histologic Type	Rad Rx Modality
Behavior Code	RX Summ – Chemo
Grade	RX Summ – Hormone
CS Tumor Size	RX Summ – BRM/Immunotherapy
CS Ext	RX Summ – Other
Regional Nodes Positive	
Regional Nodes Examined	Auditor Text Field(s)
CS LN	
CS Mets	
CS SSFs – Breast Only – SSFs; 1 (ER), 2 (PR), 15 (HER2)	

Appendix D

Data Items to be Validated – E-Pathology Review

Data Items to be Validated E-Path Review
Date of DX
Primary Site
Laterality
Histologic Type
Behavior Code
Grade
CS Tumor Size (as available)
CS Ext (as available)
Regional Nodes Positive (as available)
Regional Nodes Examined (as available)
CS LN (as available)
Auditor Text Field(s)

Appendix E

Florida Statewide Cancer Registry

2013 Data Validation Audit with E-Path Verification – Facility Information Sheet

The Florida Cancer Data System (FCDS) is charged with providing the highest quality data possible for annual cancer case reporting to the Florida Department of Health and the CDC National Program of Cancer Registries (NPCR). Data must meet rigorous quality standards to be included in local, regional, state, and national cancer rates, reports to Congress, and cancer-related health investigations. FCDS conducts many types of data processing and data quality checks including on-site and remote audits in various formats to ensure all data quality standards continue to be met and to identify areas that may require further education and training.

A Re-Abstracting (Data Validation) Audit will be performed for this facility using electronic copies of primary medical record documents submitted by this facility (electronic pathology reports plus cancer registry abstracts). The audit has been designed to assess the quality of abstracting and the accuracy of coded data items for cases submitted to the Florida Cancer Data System (FCDS). These audits allow FCDS to assess consistency in interpretation of data definitions, adherence to coding rules and guidelines, policies and procedures and to identify areas that require further education and training. A copy of the audit protocol is available from FCDS.

FCDS is utilizing a new approach this year, hoping to make better use of available electronic medical reports in an effort to reduce the burdens that come with on-site audits including; detailed planning, auditor travel, workspace, internet access, and other on-site coordination. There will be no in-person travel required. Code and data item reconciliation is required for each discrepant data item.

Facility and Case Selection have been stratified by 2013 reporting year caseload for primary breast cancer and primary colon cancer from calendar year 2013 diagnoses. All cases will be hospital "analytic" cases (e.g. patient was first diagnosed and/or first treated at your hospital). All cases will be audited remotely by the FCDS Audit Team.

AUDIT PROCEDURES and INSTRUCTIONS

1. **To obtain a PDF copy or to reprint this Information Sheet,** please go to the FCDS website *http://fcds.med.miami.edu* and log in to FCDS IDEA. If you have Admin or QC User Role - go to the Quality Control Menu. Select FCDS 2015 Quality Assurance Audit then select Information Sheet. A PDF version of this letter will open which can be saved and/or printed at your discretion.
2. **Each Case will undergo Two Distinct Audit Evaluations** with distinct code comparisons and "best value" resolution required.
    a. The **first evaluation** will be a review/recode of abstracted text compared to original abstract codes as a "visual review" with "data validation" of key data items. Undocumented values will be recoded as "unknown/not available". Text is a critical element in all internal FCDS data quality assessments as well as external third party data quality assessment procedures. FCDS, CDC, and the Florida Department of Health have been requiring full text documentation for key variables since 1995.
    b. The **second assessment** will be a comparison of original abstract codes compared to recoded values from the text contained within the electronic pathology report from the surgery of the primary site. This part of the re-abstracting audit will identify areas where abstractors may have incorrectly read, interpreted or coded histology/behavior/grade of tumor; overlooked key staging information included in the surgical pathology report; or missed other information when coding the original abstract.
3. **Coding Inconsistencies** will be documented and returned to the originating facility to be reconciled by a facility registrar. This does not have to be the original case abstractor as this is an audit of overall facility-submitted data quality and not the abstractor.
4. **Reconciliation of Facility-Level Data Discrepancies is required for this audit.** During this part of the audit, the originating institution has an opportunity to rebut any findings with additional documentation from the record or provide a rationale for not including required text or code(s) selected while abstracting the original cancer incident report. **Reconciliation is time sensitive**.
5. **4 Week Deadline for Reconciliation -** Facilities will have four (4) weeks to complete the reconciliation process and address any concerns or inconsistencies between the original text documentation, coded data and both sets of re-abstracted/re-coded data. The facility must select a "best value" for any data item found to have a coding and/or documentation discrepancy. If reconciliation has not been completed within this time frame, all audit recode findings will be reviewed with FCDS Review selected as "final".
6. **Final Reviews** will be conducted by the FCDS Senior Manager for Data Quality/Quality Control and Education.
7. **Audit Case Report:** Key data items will be audited following FCDS Standard Data Validation and Visual Editing Procedures with adherence to all national coding standards, rules and guidelines. Individual cases may be printed with all original and discrepant data, text, recodes, and final decisions including notes printed in a standard format that can be saved as a PDF.
8. **Facility Audit Summary Report:** Facility-specific audit summary findings will be aggregated by facility into a Facility Audit Summary Report. The report will be presented in FCDS standard format with major and minor annotated and summarized for comparison to the State Audit Summary Report. Recommendations for improvements may be included in your facility report.
9. **State Audit Summary Report:** All Facility Audit Summary Reports will be aggregated into a State Audit Summary Report.
10. **Education Planning:** Aggregate findings and recommendations will be used in planning statewide education and training events.

Questions: Please contact Steven Peace at 305-243-4601 or via email at *speace@miami.edu.*

Appendix F

Sample Auditor Orientation for Webcast

1. Contract Questions

2. Discuss Protocol-Driven Audit

3. Orientation to 2013 DX Year Audit Objectives and Facility Selection

4. Discuss Pathology Report(s) Selection and Display of Cancer Type for E-Path Coding

5. Discuss Specifics of Audit Reviews and Documentation Requirements related to this Audit
    a. Original Abstract Text Documentation
    b. Original E-Pathology Report Text
    c. Auditor Text Documentation
    d. Final Review Text Documentation

6. Discuss Alternating Abstract Review and E-Path Review for Each Case in the Audit – "blinded" reviews

7. FCDS will post a 2013 Data Quality Assurance Audit Information Sheet on the FCDS IDEA Menu. This will serve as an audit notification as well as provide information to the audited facility regarding audit reconciliation.

8. DO NOT CONTACT ANY FACILITY ABSTRACTOR, CONTRACTOR, REGISTRAR, or MANAGER

9. DO keep FCDS fully informed should you run into unusual or unforeseen circumstances during the audit

10. Auditors will be granted access to specified documents linked to each abstract to be audited

11. Re-Abstracting and Data Validation will be based only on the documents available to the auditor

12. Please adhere to ALL FCDS policy and procedures regarding secure data access using FCDS IDEA

13. FCDS will schedule an Audit Orientation for the Facilities to be Audited – you may attend as "silent"

14. You may not reproduce any abstracts, reports, or other documents in part or in total used during the audit

15. You must complete all audit-related work on or before July 31, 2015

16. Demonstration of audit data collection tool and how to access FCDS IDEA to use the audit data collection tool

17. Instructions to Auditors – DOCUMENT/DOCUMENT/DOCUMENT – YOU are the EXPERT

18. Post-Audit Requirements – NONE

19. Call Steve with any questions 305-243-4601 or email at *speace@miami.edu*

20. Questions?

Appendix G
Sample Reports

Sample Cover Letter

FCDS Florida Cancer Data System

Florida Statewide Cancer Registry

Dear Cancer Registry Manager:

Your Facility was selected to participate in the 2015 FCDS Data Quality Audit of a sample of cancer cases diagnosed and treated at your facility during calendar year 2013. The audit is complete and final reports are available via the secure data portal, FCDS IDEA for individuals with the IDEA User Role HOSPADMIN. Some reports are highly confidential. Others are for summary and comparison. The annual data quality audit is a state and federal requirement for the Florida Cancer Data System to ensure compliance with the state mandated 5-year FCDS Data Quality Audit Cycle and the CDC National Program of Cancer Registries - Program Requirements.

METHOD: The Audit included recoding of critical data elements and e-path coding of a sample of cancer cases reported to the Florida Cancer Data System (FCDS) from each hospital over the course of a 5-year cycle and as part of the legislatively mandated Florida Cancer Reporting Requirements. The audit was 100% electronic.

FACILITY & CASE SELECTION: Facility and Case Selection have been stratified by 2013 reporting year caseload for primary breast cancer and primary colon cancer from calendar year 2013 diagnoses. Therefore, a facility may have been selected for only breast cancer audit or only colon cancer audit based on the available cases meeting the each stratum. All cases will be hospital "analytic" cases (e.g. patient was first diagnosed and/or first treated at your hospital).

ORIGINAL AUDIT REVIEW: A qualified Certified Tumor Registrar (CTR) auditor experienced in performing data quality audit reviews was responsible for examining each case in the selection, recoding specific variables based on text submitted in the original abstract using standard rules and guidelines, and included a comparison to data from electronic pathology report(s) submitted to FCDS during routine e-path reporting.

FACILITY-LEVEL RECONCILIATION: Each facility was required to address each and every data value or coding inconsistency with a coded "best value" determination. This was performed by a qualified abstractor designated by each facility and required a rationale and "best value" returned via secure FCDS IDEA - QC Audit.

FCDS FINAL RECONCILIATION: FCDS CTR Senior Staff evaluated each case and each data item value inconsistency to make a final "best value" determination based on national abstracting standards used by registrars every day. Each case may have been reviewed multiple times prior to this audit; at time of initial receipt by FCDS including national standard EDITS, at time of routine QC Visual Review, and during FCDS Consolidation of Data to ensure the data originally submitted was sufficient to meet minimum guidelines for reporting. For purposes of this audit, each case was again reviewed a minimum of three (3) times by experienced CTR staff. Please see General Summary Findings.

AUDIT FINAL REPORTS (Non-Confidential): Summary Reports are non-confidential and do not include any patient health information or other personal identifying data. Summary Reports include a comparison of how well your facility did in comparison to the state distribution of similar errors based on final reconciliation values. Facility-specific reports are not shared with any other facility. Aggregate and comparison summary reports are now available and do include non-identifiable data (audit outcomes) from your facility combined with others. (text errors, coding errors, summary)

AUDIT FINAL REPORTS (Confidential): Confidential, patient-specific reports of each data item, value, reconciliation, comments, and final "best value" selection and rationale are provided for each patient included in the audit via FCDS IDEA. FCDS recommends that each facility print a copy of each individual abstract audit report and review the final reconciliation determination, then make changes to your in-house database to match the final value. Individual patient-specific reports are highly confidential and should not be distributed outside your organization or registry. Review of confidential reports with cancer registry abstractors is recommended. (patient-confidential individual reports)

ACCESS TO AUDIT REPORTS: You may access, save and print any and all audit-related reports for your facility via FCDS IDEA. You must have HOSPADMIN Role in FCDS IDEA to access reports.

QUESTIONS: Please contact Steven Peace, CTR at (305)243-4601 or speace@miami.edu with any questions.

CONFIDENTIAL - Sample Confidential Reports Not Available – CONFIDENTIAL

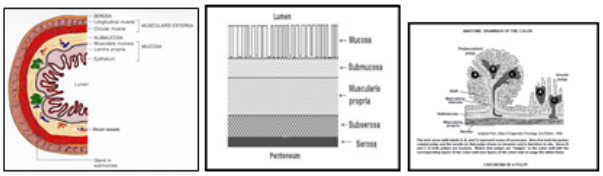
Sample General Summary Findings and Cancer-Specific Findings

GENERAL SUMMARY FINDINGS

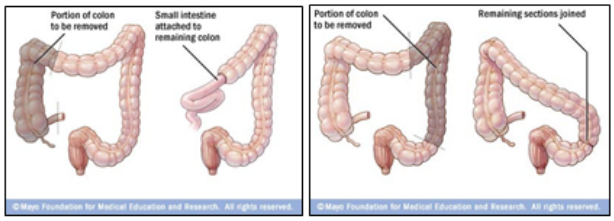
1. Text submitted in abstract cuts off without registrar knowing or paying attention to where it cuts off – vendors allow overflow into "notes" fields and usually color-code when included/not included – and FCDS does not get the full context or content of the section that overflows to the "notes".
2. Diagnostic Imaging shows primary tumor and/or metastasis before any biopsy or resection attempted. The imaging date is the date of dx, not the date of first biopsy or resection.
3. Adjacent versus Overlapping Primary Site/SubSite when first biopsy or scope indicates one subsite and the resection specimen another – need to validate with surgical report as to what is primary site
4. Scope of Regional Lymph Node Dissection miscoded – registrars still find this item confusing to code
5. Instances where there are multiple codes, some a bit more specific than others, that describe the same tumor extension or level of nodal metastasis – when the original abstract has 1 code and the Reabstract another – was very lenient if resultant T or N or SS2000 was same with either code even if 1 was more specific – took all into account and agreed with original abstract in most every case.

COLON-SPECIFIC FINDINGS

1. Primary Site Cecum versus Ascending Colon – was very lenient when adjacent sites were the issue – registrars should take this information from the surgical resection report (not path report) since the surgeon is looking at the anatomic landmarks before and during surgery – and the pathologist only gets a segment of colon.
2. Low Grade/High Grade for Colon Sites are to be coded as "2" and "4" respectively. Codes for low grade and high grade for breast and prostate cancers are the only sites where low grade = 1 and high grade = 3.
3. Derived T3 includes CS Extension codes 400 and 450. However, registrars are inconsistent even within same institution with regard to when they assign code 400 and when they assign code 450 for CS Extension. This is partially a matter of correctly referencing the layers of the bowel wall – but also misunderstanding terminology. However, when deriving SS2000 there is a major difference between local and regional direct extension depending on whether or not the neoplasm extended entirely through the bowel wall into adjacent tissue or fat (450 - regional) or when only subserosal fat or subserosal adipose tissue is invaded (400 - local). Refer to layers of colon to ensure this is coded properly. Remember, the vast majority of colon neoplasms grow from the inside of the colon wall outward toward the serosa. Subserosal fat is the fat between the submucosa and serosa, not the fat that is on the outside of the colon which is pericolonic, pericolic or adjacent fat – refer to images for reference as this is an important marker for prognosis.



4. CS Lymph Nodes 110 and 210 are more specific than code 300 – but, all result in node+ stage. There is a note in the CS Lymph Nodes that states, "Note 4: The number of positive regional nodes is required to calculate the correct N category for this schema. Use codes 400-480 when the pathology report assigns an N1 or N2 category but does not specify the number of nodes involved, or the record identifies an N1 or N2 category but the specific information about number of nodes involved is not available. Use codes 110-300 rather than codes 400-480 when information about the number of positive nodes is available, or when nodes are clinically positive but not removed for examination."
5. Registrars often miscode surgical procedure as 30 (segmental/less than hemicolectomy) and 40 (hemicolectomy) with 50 being total colectomy. Need to check operative report to ensure the procedure is coded correctly. Note that hemicolectomy procedure must include at least 1 flexure. A transverse colectomy does not include either flexure unless the neoplasm is close to or involves the flexure removed.



6. Occasionally a vendor might drop 99 as default into a treatment field when it should be 00. Need to be alert to what the vendor sends to FCDS as much as what gets sent to NCDB or other Calls for Data.
7. There were many cases where chemotherapy was recommended as is standard for any Stage II or higher, but the recommendation was not coded nor was the treatment. Stage II cases include any T3 or T4 plus or minus positive nodes. These are missed adjuvant chemotherapy based on standard of care in most cases.

BREAST-SPECIFIC FINDINGS

1. Mammography Date is routinely NOT used as Diagnosis Date even when it is clear there is a mass in the breast, not a cyst or fibrocystic disease, but a mass. This is a diagnostic imaging report that is later confirmed by biopsy/resection. Use the mammography date when the interpretation describes tumor.
2. ER/PR/HER2 are not always documented in text – these must be documented clearly without run-on report that does not clearly delineate which result goes with which test. Oncotype DX should not be used as ER/PR or HER2 result for any case as this is a proprietary genetic testing sequence and does not have universal agreement on what thresholds for positive and negative are or should be in this context.
3. Scope Regional Lymph Node Surgery for patients with or without Sentinel Node Biopsy are frequently miscoded – across the board. Please use the notes in the FCDS DAM to clarify which code should be used.
4. Surgery codes for mastectomy plus or minus removal of contralateral breast are not consistently applied and registrars frequently code to more general surgery code. Did not count off for these.
5. Coding Grade for Breast uses Low Grade = 1 and High Grade = 3. Only breast and prostate use these codes. All other solid tumors assign low grade = 2 and high grade = 4.
6. There were many cases where chemotherapy was recommended as is standard for any node positive tumor. Similarly miss recommended hormone and/or immunotherapy based on age of patient for ER/PR+ and/or missing Herceptin for HER2+, but the recommendation was not coded nor was the treatment. These are missed adjuvant chemotherapy based on standard of care in most cases.

Appendix H

Audit Timeline

11/2014	12/2014	01/2015	02/2015	03/2015	03/2015	04/2015	05/2015	06/2015	07/2015
Protocol Updates	Final Protocol								
		Software Updates	Software Updates						
			Identify Audit Team	Audit Orientation Webcast					
					Audit	Audit			
						Reconciliation	Reconciliation		
								Final Review	
									Update FCDS Record
								Preliminary Audit Report	Final Audit Report