**2021 Field Testing**

**Protocol and Appendices**

**June 2021 (Updated October 2021)**

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**Introduction**

1. **Background**

Field testing is now required on any new data items that are being introduced to the registry community. Field testing is also being used to determine how well registrars understand updates to coding instructions for current site-specific data items (SSDIs). This protocol addresses the new data items proposed for implementation in 2023 that are being proposed by the NAACCR SSDI workgroup, SEER, NPCR and AJCC/CoC. It also includes SSDIs and several other data items that standard setters are interested in collecting but need to determine their availability.

1. **Objectives**

Field testing will

* Assess the availability of several data items that standard setters are interested in collecting (accessibility)
* Assess how well registrars can code the proposed new data items based on the current codes and definitions (feasibility)
  + Provide feedback on additional coding instructions needed or changes to the proposed codes and code definitions

1. **Design**
   1. Field Testing Mechanism
      * The 2021 Field Testing will be a web-based activity
      * Participants must use a computer with access to the Internet
      * The cases will be placed on the SEER Reliability website
      * Participants will complete the field testing online
   2. Data items and Questions: There are two major groups for data items being tested. First group is for proposed new data items and the second group is for accessibility testing to determine if information is widely available for a data item that is being considered.

* Group 1: Proposed new data items (these would all be SSDIs)
  + ER Summary after neoadjuvant therapy (Breast Schema)
    - Per communication from AJCC/CoC on 10/11/2021, this proposed SSDI will not be in the 2021 Field Study
  + PR Summary after neoadjuvant therapy (Breast Schema)
    - Per communication from AJCC/CoC on 10/11/2021, this proposed SSDI will not be in the 2021 Field Study
  + HER2 Summary after neoadjuvant therapy (Breast Schema)
    - Per communication from AJCC/CoC on 10/11/2021, this proposed SSDI will not be in the 2021 Field Study
  + Primary Tumor Location (Brain, CNS Other and Intracranial Gland schemas)
  + Histology Subtype (Appendix schema)
  + Primary Site Surgery Codes (Melanoma Skin schema)
  + Margin Measurement (Melanoma Skin schema)
* Group 2: Data items being tested for accessibility (availability)
  + Anus: p16
  + Anus: HIV
    - Per communication from AJCC/CoC on 10/11/2021, this data item will not be in the 2021 Field Study
  + Appendix CA 19-9
    - Per communication from AJCC/CoC on 10/11/2021, this data item will not be in the 2021 Field Study
  + Lung: PD-L1
  + Melanoma Skin: PD-L1
  + Colon and Rectum: HER2

***Note:* The remainder of this protocol will cover the data items that are included in the 2021 Field Testing. Protocol was updated on 10/12/2021 to incorporate the changes received from AJCC/CoC on 10/11/2021 (call for cases was not updated since that was sent out prior to the changes).**

* There will be 5 groups of cases
  + Each group will have 4 unique cases for Primary Tumor Location
    - Registrars must complete a minimum of 1 group (4 cases) but can do up to 5 groups (20 cases) for this proposed SSDI
  + In addition, there will be three sets of 5 multiple choice questions, one for each of the Histology Subtype, Primary Site Surgery Codes, and the Margin Measurement
  + Registrars will answer one set of questions for each of the 4 potential SSDIs in Group 2
    - The target is to accrue at least 500 participants so that each data item is completed approximately 100 times.
  1. Invitation to Participate
     + The field testing will be open to all cancer registrars in the United States and Canada

Invitation to Participate is in APPENDIX A

* 1. Account Creation
     + Account creation will take place via the Web
     + Participants who have not participated in a previous SEER reliability study will need to create an account
     + The SEER Reliability website will open for account creation and registration for the field testing on October 15, 2021. Field testing opens November 1, 2021

1. **Case Assignment**
2. Completion of 1 set ( 4 cases, 3 sets of multiple choice questions, and questions for 4 potential SSDIs) is required
3. Registrars may complete additional (up to 4 more sets of cases [4 cases each] for the Primary Tumor Location SSDI)
4. **Field Testing Process**
   * + 1. **Part I:** The field testing will be conducted by having participants assign codes for the following data items listed by schema, which is called *feasibility testing*. Participants will have all available case documents and applicable resources for review. Allowable codes for the SSDIs are in the Functional Requirements Document (see APPENDIX B for detailed list of allowable codes for data items. Allowable codes have been restricted to decrease the number of data entry errors).

* Appendix Schema
  + Histology subtype (proposed SSDI)
* Brain, CNS Other and Intracranial Gland Schemas
  + Primary Tumor Location (proposed SSDI)
* Melanoma Skin Schema
  + Primary Site Surgery Codes (proposed update to current surgery codes)
  + Margin Measurement (proposed SSDI)
    - 1. **Part II:** The field testing will also include *accessibility* testing, which will ask questions about the availability of information. This is a new addition to the Field Testing process. For the 2021 study, we have four data items
* Anus: p16
* Lung: PD-L1
* Melanoma Skin: PD-L1
* Colon and Rectum: HER2

1. **Field Testing Participants**
   1. Eligibility: The field testing is open to all cancer registrars in the United States and Canada
   2. Requirements for Participation

* Participants in the field testing must use a computer with Internet access
* The assessment will be web-based and located on the SEER Reliability website
* All test cases should be completed by December 15, 2021
* NCRA will grant continuing education 3 (CEU) credits to the participants for completion of one set. Registrars can earn up to 4 additional CEUs for 16 additional Primary Tumor Location cases (1 CEU per 1 group, which is 4 cases). Certificates showing the event number and the number of CEU’s will be made available to participants following the field testing.

1. **Preparation for the Study**
2. A call for cases will be conducted August 3, 2021. The call will cover all the hospital and central registries in the US and Canada.
3. Each registry will be asked to submit at least one record for each SSDI.
   * For the field testing, the cases will include all the information that was provided by the registry
4. A case number will be assigned for each patient medical record received following the call for cases.
   * 1. For each patient medical record, a database will be developed that includes
        1. The central registry identifier of the registry transmitting the case
        2. Cancer site
        3. Data item
     2. Once a patient medical record is received, the case will be reviewed by at least three CTRS, who will determine which cases are included
     3. For the chosen cases, the following preparation will be done
        1. Redact personal identifiers
        2. Redact facility identifiers
        3. Redaction will occur on a rolling basis as cases are submitted from registries
        4. Add header with case identification to each record
        5. Save the file using a standard naming convention
        6. Each case will be coded by at least 3 CTRs using the proposed codes and coding definition and a preferred answer will be determined
5. The preferred answers will be entered into an Excel spreadsheet or Access database and provided to IMS. They can be included in the software so that participants can see the preferred answers. IMS can create flags for correct/incorrect answers as part of the analytic file
6. The final dataset of patient medical records selected for the field testing will include the following data elements: see **Appendix D**
7. The preferred answers will be made available online to participants at the time a case is completed. Participants will have the opportunity to comment on the answers and on the quality of SSDI information.
8. IMS will delete any files after the field testing closes
9. **Data Preparation and Analysis**
10. Calculate percent agreement between abstractor assigned values with “preferred value.” Percent agreement will be measured by the number of cases where values match the gold standard divided by the total number of cases and also using the kappa statistic. Frequency tables will be created to show where the mismatches are occurring.
11. The analysis will be performed for all the data items
12. Summarize the comments received from the field testing participants.
13. **Field Testing Timetable**

| **Task** | **Date** |
| --- | --- |
| Call for Cases | August 3, 2021 |
| Cases due to from registries | September 1, 2021 |
| Cases redaction and review | August-September 2021 |
| Final case selection | September 15, 2021 |
| Develop preferred answers and rationales | September 2021 |
| Adjudication of preferred answers | September-October 15, 2021 |
| Send out invitation to participate | October 1, 2021 |
| Selection of preferred answers after adjudication | October 15-October 23, 2021 |
| Reliability website opened for account creation and registration for field testing | October 15, 2021 |
| Preferred answers, rationale and cases due to IMS | October 24, 2021 |
| Case files loaded into reliability software | October 25-October 31 |
| Field Testing opens to participants | November 1-December 15, 2021 |
| Data processing and analysis | December 15, 2020-January 31, 2022 |
| Present findings to MLTG | February 2022 |

1. **Appendices**
2. **Invitation to Participate:** Letter to registries to informthem about the field testing.
3. **Functional Requirements Document:** Specifications for set-up of reliability software including questions and data field restrictions.
4. **Call for Cases:** Letter to registries with specifications on which cases we would like them to send and data transfer instructions.
5. **Data Items to be Redacted from Case Files**
6. **Introduction for the SEER Reliability Website:** This appendix is for what the registrars will see when they first login into the Field Testing page on the SEER Reliability Website

**Appendix A: Invitation to Participate**



FROM: Serban Negoita (NCI SEER): Co-chair NAACCR Mid-Level Tactical Group

Manxia Wu (NPCR): Co-chair NAACCR Mid-Level Tactical Group

SUBJECT: 2021 Field Testing

DATE: October 14, 2021

Hello,

The Senior-Level and Mid-Level Tactical Groups (SLTG and MLTG), which includes representations from all standard setters (Canada, CoC, NPCR, and SEER), along with representatives from AJCC, NCRA, and NAACCR, now requires that field testing be done for proposed new data items, or major changes, before implementation in the registry field. For 2019 and 2020, this process included “feasibility testing,” which is evaluating proposed site-specific data items (SSDIs), including clarifying codes and coding instructions, before implementation.

For 2021 field testing, we are adding a new section which is for “accessibility testing,” to determine if information for a potential data item is available in the registry community prior to developing the data item.

The SLTG and MLTG strongly encourage your participation in this effort, which we believe will facilitate better communication with registrars in the field and provide critical information to groups/standard setters working on these proposed and potential data items.

The Field Testing will be implemented using the same software used for the SEER Reliability Studies, with some modifications. **Participation in the** **Field Testing will not be required by any of the standard setters but is strongly encouraged. This is your chance to comment on data items prior to implementation.**

There are three new SSDIs and a proposed update to an existing data item that are being proposed for implementation in 2023.

* Primary Tumor Location (Brain, CNS Other and Intracranial Gland schemas)
* Histology Subtype (Appendix schema)
* Clinical Surgical Margins (Melanoma Skin schema)
* Primary Site Surgery Codes (Melanoma Skin Schema) (proposed update to existing primary site surgery codes)

For all data items in the feasibility section of the study, participants will be provided the preferred answer and rationale after completion of each question, along with an opportunity to comment on the preferred answer and rationale. In addition, there will be questions regarding the Field Test process and recommendations for future improvements.

The new portion of this study is the accessibility section. This portion of the Field Testing will ask questions about whether particular information is available for a potential SSDI. These will be questions only (no coding). The purpose of this portion of the Field Testing is to determine if the information is widely available prior to developing a new data item.

Each of these sections have multiple questions about the frequency of the specific cancer and if the types of reports are available. To find this information would require searching through your databases. If you are limited to time yet know that this information is available in your registry, please provide this information in the last question for that test, which is (for example): Any comments regarding p16 for Anus. Listed here are the 4 potential SSDIs that we are looking at this year.

* Anus: p16
* Lung: PD-L1
* Melanoma Skin: PD-L1
* Colon and Rectum: HER2

*Note: The earliest these would be developed into SSDIs if found to be readily available in the cancer registry community would be 2024. They would have to go through the 2022 Field Testing for “Feasibility testing” first to evaluate the codes and coding instructions.*

Continuing Educate (CE) credits will be available.

The field testing will take place from 8 a.m. EDT, **November 1, 2021** to 12:00 a.m. EDT, **December 15, 2021.** Participants must have access to the SEER reliability studies site (<https://reliability.seer.cancer.gov>) during this period.

* Registration for Field Testing will open on October 15, 2021

Note that since the objectives of this field testing are to determine how well the new data items are understood or if they are available, **individual** **results will remain confidential** and not released. Results will be de-identified before analysis.

Now is the time to recruit facility reporters and your registry staff to participate. All participants will be using the SEER Reliability software. If you have participated in a previous reliability study (2014 or later), use your same login. If you have not participated in a previous reliability study, you will need to create an account. To create a new account please follow the Create an Account link on the sign-in page (<https://reliability.seer.cancer.gov>).

Please email [reliability@imsweb.com](mailto:reliability@imsweb.com) for technical questions and Jennifer Ruhl ([ruhlj@mail.nih.gov](mailto:ruhlj@mail.nih.gov)), co-chair of the SSDI work group, for related questions.

We look forward to your participation and feedback.

**Appendix B: Functional Requirements Document**

**Section A- Elements required for set up of a study**

1. Name of study: 2021 Field Testing
2. Study Dates
   1. Start showing dates on SEER website: October 15, 2021
   2. Open date: November 1, 2021
   3. Close date: December 15, 2021
   4. Hide from user’s date: January 4, 2022
   5. Hide from everyone date: January 4, 2022
3. Text for Study Overview Page: October 10, 2021
4. Demographics questions (in addition automatic fields which are: Primary region, Primary state, Registry type, Hospital CoC accreditation, Organization, Institute)

|  |  |  |  |
| --- | --- | --- | --- |
| **Label of question**  **(as you would like it to appear on website)** | **Data Type** | **Is this a required field?** | **Constraints/limits you would like the web site to impose on the answer** |
| Are you a CTR? | Drop down list | Yes | Yes  No |
| How many years of experience do you have in coding? | Free text | Yes | Numeric between 0 and 99 |
| How many cases per year do you abstract personally | Drop down list | Yes | None  1 – 250  251 – 500  501 - 1000  1001 – 2000  2001 or more  Unknown (values to potentially change) |
| How many cases per year do you assign AJCC 8th edition staging personally while abstracting | Drop down list | Yes | None  1 – 250  251 – 500  501 - 1000  1001 – 2000  2001 or more  Unknown (values to potentially change)  Do not assign AJCC stage |

1. How many practice cases: None
2. How many regular cases?

A total of 20 cases/ 1 data item for the proposed SSDI: Primary Tumor Location, with 20 cases/ 1 data item being divided into 5 groups, each group having 4 cases/ 1 data item.

1. How many multiple choice questions
   1. 3 sets of 5 multiple choice questions (Histology Subtype, Primary Site Surgery Codes, and Clinical Surgical Margins)
2. Medical records for all cases – these will be delivered from registries to IMS in PDF image format, in rolling deliveries, with the last case to be delivered by September 3, 2021.
3. Data items for each case: These will all be required and drop-down menus (no blanks allowed). ***The data items and valid values for each data item are site specific*** and are specified in the Table below.

| Label of Data Item | Data Type | Data Item Required | EOD Schema | Allowable Value |
| --- | --- | --- | --- | --- |
| Primary Tumor Location | Drop down | Yes | Brain, CNS Other and Intracranial Gland | 00, 10, 20, 30, 40, 50, 60, 70, 75, 80, 85, 99 |
| Histology Subtype | Drop down | Yes | Appendix | A, B, C, D, E |
| Primary Site Surgery Codes | Drop Down | Yes | Melanoma Skin | B000, B100, B110, B120, B130, B140, B200, B210, B220, B221, B222, B230, B231, B232, B240, B300, B310, B320, B500, B510, B520, B521, B522, B530, B531, B532, B540, B550, B600, B900, B990, Not applicable |
| Margin Measurement | Drop Down | Yes | Melanoma Skin | 0.1-9.9, XX.1, XX.7, XX.8, XX.9 |

1. We are now including questions regarding whether information is available for specific information. This is for the accessibility portion of the Field Testing.

**Data Item #1:**

| **Question #** | **Label of question**  **(as you would like it to appear on website)** | **Data Type** | **Is this a required field?** | **Constraints/limits you would like the web site to impose on the answer** |
| --- | --- | --- | --- | --- |
| 1 | How many cases of anal cancer (squamous cell carcinoma) in the last 6 months | Number/ Text | No | None |
| 2 | How many of those anal cancer (squamous cell carcinoma) cases in the last 6 months had HPV status mentioned | Number/ Text | No | None |
| 3 | How many of those anal cancer cases in the last 6 months mentioned a history of other squamous cell HPV-related cancer in the genital area (vulva, vagina, cervix, penis) | Number/ Text | No | None |
| 4 | How many of those anal cancer cases in the last 6 months mentioned a history of other squamous cell HPV related cancers in Head and Neck sites | Number/ Text | No | None |
| 5 | Any comments regarding p16 for Anus | Text | No | None |

**Data Item #2:**

| **Question #** | **Label of question**  **(as you would like it to appear on website)** | **Data Type** | **Is this a required field?** | **Constraints/limits you would like the web site to impose on the answer** |
| --- | --- | --- | --- | --- |
| 1 | How many cases of lung cancer in the last 6 months | Number/ Text | No | None |
| 2 | How many of those lung cancer cases in the last 6 months had PD-L1 IHC status or interpretation (positive, negative, or cannot be determined/indeterminate) mentioned | Number/ Text | No | None |
| 3 | How many of those lung cancer cases in the last 6 months had PD-L1 IHC percentage of tumor cells with staining (TPS) mentioned | Number/ Text | No | None |
| 4 | How many of those lung cancer cases in the last 6 months had PD-L1 IHC combined number of tumor and immune cells with staining per 100 tumor cells (CPS) mentioned | Number/ Text | No | None |
| 5 | How many of those lung cancer cases in the last 6 months had PD-L1 IHC percentage of tumor associated immune cells with staining mentioned | Number/ Text | No | None |
| 6 | How many of those lung cancer cases in the last 6 months had PD-L1 IHC percentage of tumor area occupied by tumor-associated immune cells mentioned | Number/ Text | No | None |
| 7 | How many of those lung cancer cases in the last 6 months had PD-L1 IHC antibody (22C3, SP142, SP263, 28-8, Other) mentioned | Number/ Text | No | None |
| 8 | How many of those lung cancer cases in the last 6 months had PD-L1 IHC assay information (FDA clear test vs. laboratory-developed test) mentioned | Number/ Text | No | None |
| 9 | Any comments regarding PD-L1 IHC for lung cancer | Text | No | None |

**Data Item #3:**

| **Question #** | **Label of question**  **(as you would like it to appear on website)** | **Data Type** | **Is this a required field?** | **Constraints/limits you would like the web site to impose on the answer** |
| --- | --- | --- | --- | --- |
| 1 | How many cases of cutaneous melanoma in the last 6 months | Number/ Text | No | None |
| 2 | How many of those cutaneous melanoma cases in the last 6 months had PD-L1 IHC status or interpretation (positive, negative, or cannot be determined/indeterminate) mentioned | Number/ Text | No | None |
| 3 | How many of those cutaneous melanoma cases in the last 6 months had PD-L1 IHC percentage of tumor cells with staining (TPS) mentioned | Number/ Text | No | None |
| 4 | How many of those cutaneous melanoma cases in the last 6 months had PD-L1 IHC combined number of tumor and immune cells with staining per 100 tumor cells (CPS) mentioned | Number/ Text | No | None |
| 5 | How many of those cutaneous melanoma cases in the last 6 months had PD-L1 IHC percentage of tumor-associated immune cells with staining mentioned | Number/ Text | No | None |
| 6 | How many of those cutaneous melanoma cases in the last 6 months had PD-L1 IHC percentage of tumor area occupied by tumor-associated immune cells mentioned | Number/ Text | No | None |
| 7 | How many of those cutaneous melanoma cases in the last 6 months had PD-L1 IHC antibody (22C3, SP142, SP263, 28-8, Other) mentioned | Number/ Text | No | None |
| 8 | How many of those cutaneous melanoma cases in the last 6 months had PD-L1 IHC assay information (FDA clear test vs. laboratory-developed test) mentioned | Number/ Text | No | None |
| 9 | Any comments regarding PD-L1 IHC for cutaneous melanoma | Text | No | None |

**Data Item #4:**

| **Question #** | **Label of question**  **(as you would like it to appear on website)** | **Data Type** | **Is this a required field?** | **Constraints/limits you would like the web site to impose on the answer** |
| --- | --- | --- | --- | --- |
| 1 | How many cases of colon and rectum cancer in the last 6 months | Number/ Text | No | None |
| 2 | How many of those colon and rectum cancer cases in the last 6 months had a HER2 | Number/ Text | No | None |
| 3 | Any comments regarding HER2 for colon and rectum | Text | No | None |

1. Along with each of the data items, each participant be given an opportunity to provide comments on the preferred answer and rationale. After that, additional questions will come up

| **Label of question**  **(as you would like it to appear on website)** | **Data Type** | **Is this a required field?** | **Constraints/limits you would like the web site to impose on the answer** |
| --- | --- | --- | --- |
| Were the codes, code definitions and coding instructions clear | Yes/No | No | If they answer No, add a free text box labeled “Please tell us why” |
| Do you have any further suggestions on how to improve this data item | Free text | No |  |
| If hospital registrar, is this information typically available at your facility | Yes/No | No |  |

1. Any validation that needs to happen for each data item: Every data item is required, and it must be non-blank. User must pick a value from each drop-down list.
2. Number of cases needed for completion: 1 set (4 cases /per data item) with an option to complete up to 4 additional sets (up to 20 cases/ 1 data item). In addition to completing at least one set of cases, registrars will also complete three sets of 5 multiple choice questions and answer 4 additional questions about availability.
3. Cases done in order? No
4. Preferred answers? Yes – the preferred answers will be delivered to IMS in MS Excel format and will be delivered 1 month prior to the date when we want our users to see the preferred answers on the website. Rationale will also be provided in the same Excel sheet.
5. Which institutions/registries involved? All institutions/registries may participate.
6. Expert version of the study? No
7. Certificate
   1. Field Study Testing - Accessibility and Feasibility of proposed and potential new data items
   2. CEUs: 3 per Group
      1. 4 additional CEUs available for completing 4 additional sets of Primary Tumor Location
   3. NCRA event number: 2021-186
   4. Name for signature: Serban Negoita (SEER) and Manxia Wu (NPCR)
8. Case groups – CTR’s are responsible for creating the groups. IMS will receive 20 cases clearly marked with which case goes with which group. IMS will implement set by keeping track of which case goes with which set and assigning a new user to the next available set. When a user gets assigned to a set, they must complete the cases in that group in order to earn CEUs. If they wish to complete a second set, the software will just assign them the next available set that is not the one they just completed.
9. Post-study poll

|  |  |  |  |
| --- | --- | --- | --- |
| **Label of question**  **(as you would like it to appear on website)** | **Data Type** | **Is this a required field?** | **Constraints/limits you would like the web site to impose on the answer** |
| Did you find the SEER software easy to use? | Yes/No | No | If they answer No, add a free text box labeled “Please tell us why” |
| What do you think of the field testing process? | Free text | No |  |
| Do you have any suggestions on how to improve the field testing process? | Free text | No |  |

**Appendix C: Call for Cases**

FROM: Serban Negoita (NCI SEER): Co-chair NAACCR Mid-Level Tactical Group

Manxia Wu (NPCR): Co-chair NAACCR Mid-Level Tactical Group

SUBJECT: 2021 Field Testing

DATE: August 9, 2021

The Senior-Level and Mid-Level Tactical Groups are conducting field testing to determine how well proposed SSDIs (implementation 2023) are developed and to collect feedback from registrars prior to implementation of these data items. The field test assessments ask registrars to code the proposed SSDIs using original medical records. Records are not to be submitted without following the specific instructions below.

This field test will provide the NAACCR SSDI work group and the Standard Setters information for developing and refining new proposed SSDIs and other data items.

1. **Description of Cases Requested**

**Confidentiality**

**Cases must be de-identified before submitting.  Remove/delete all personal identifying information to protect privacy and assure confidentiality.**

**Personal identifiers include:**

* **Patient name**
* **Physician names**
* **Healthcare facility name**
* **Any address and/or geographic information (street, city, state, zip code)**
* **Telephone numbers**
* **Date of birth**
* **Social security number**
* **Medical record number**
* **Any other identifying information**

**Remove or delete all personal identifiers from each page of the medical record.**

1. **Neoplasm type:** Submit at least 1 case for the three data items listed below when possible. There is no minimum or maximum number of cases that can be sent. The cases should be reportable cases that are **single primaries only**. The most relevant reports that are needed are in parentheses.
   1. Breast: ER Summary/PR Summary/HER2Summary **AFTER** neoadjuvant therapy (pathology reports, including special studies, addendums)
      1. Breast cases that have neoadjuvant therapy and ER/PR/HER2 are done **after** neoadjuvant therapy
2. **Difficulty Level:** Most of the cases should be among the common, not rare or difficult. These cases should be typical cases registries can expect in their overall caseload.
3. **Diagnosis Date:** Please send 2021 cases if possible. If enough 2021 cases cannot be found, it is acceptable to send 2019-2020 cases.
4. **Required Parts of Medical Record**: Please include all records that would be available to an abstractor collecting the case at the facility.

**The case files could include information such as the following:**

* 1. Discharge Summary(ies)
  2. History and Physical(s)
  3. Consultation(s)
  4. Imaging Report(s), in chest/abdominal/pelvic CT and PET-CT scans
  5. Procedure Report(s)
  6. Operative Report(s)
  7. Pathology Report(s) (i.e. Special studies, Addendums, etc.)
  8. Immunophenotyping (flow cytometry and/or immunohistochemistry)
  9. Genetic testing
  10. Reports on tests frequently occurring outside the hospital (i.e. cytogenetics)

1. **Case Preparation**

* Electronic submission to IMS (see instructions for how to send cases below). If you do not have cases in electronic format, then please scan the records into pdf or OCR format to send electronically.
* Remove all personal identifiers from all reports.
* Number the cases sequentially, beginning with Case 1 (Case 1, Case 2, Case 3, etc.) on electronic file name, not on inside of document.
* Please retain for future uses, the patient ID or medical record number or any other useful information that will help you identify the original source. Please do not transmit these numbers.

**Case Submission:** Please **do not hold** cases until the deadline.  Send cases as soon as you locate them.

**Last Day to Submit Cases:          September 3, 2021**

**When to send:** Please send cases as they are identified. Multiple submissions are preferred rather than waiting to send them all right before the deadline

**How to send:                                 Instructions for submitting cases**

**Case data will be collected by Information Management Services, Inc., who provides technical support for SEER.**

**When you are ready to transmit the case data, please email Nicki Schussler (**[**SchusslerN@imsweb.com**](mailto:SchusslerN@imsweb.com)**).  Please include your organization’s name and that the data is ready for transmission. DO NOT include the case data on this initial email.**

**You will then receive an email via the IMS Encrypted data exchange server referencing the call for data.  Please respond to this email from the encrypted data exchange, attaching your data file.  If you are required to encrypt the file by your organization’s policies, please provide a phone number and Nicki will contact you to get the password.**

**Appendix D: Data Items to be captured from Case Files**

These data items shall be stored in a database to be merged back to the original case.

| **Variable number** | | **Variable name** | **Definition** |
| --- | --- | --- | --- |
| 01 | caseidm | | Case identification number of the case/medical record receive following the August 2021 call for cases; standard format CXXZZN CXX is the primary site; ZZ registry identifier; N – case count. |
| 02 | caseidh | | Same as the file name |
| 03 | registryid | | Same as the NAACCR data element |
| 04 | schema\_id | | NAACCR data element |
| 05 | Groups | | 5 |
| 06 | Primary Tumor Location | | Preferred value see list of valid values |
| 07 | Histology Subtype | | Preferred value see list of valid values |
| 08 | Primary Site Surgery Codes | | Preferred value see list of valid values |
| 09 | Margin Measurement | | Preferred value see list of valid values |

**Appendix E: Study Overview (SEER Reliability Website)**

Study overview

Field Study Purpose

Due to the major changes and delays for 2018 implementation, the NAACCR mid-level tactical group (MLTG) mandated that proposed new data items need to be evaluated for availability and feasibility and tested prior to implementation. This process may also be used to evaluate current data items. There are several reasons for this

* Determine if the information for a potential new data item is available
* Provide registrars the opportunity to evaluate codes and coding instructions prior to implementation
* Assist standard setters in determining if a proposed data item should be implemented
* Indicate educational needs in coding data items
* Allow standard setters a mechanism to test current data items known to be problematic

For the 2021 Field Testing, there are now 2 major categories of data items being tested

* Accessibility (Potential SSDIs): For these data items, there is interest in collecting relevant information; however, it is not known how frequent this information is available in the cancer registry community
  + For these data items, registrars will be asked to look at their records to determine if the information is available
  + If it is found that these data items are readily available, then they will be moved to Feasibility portion of the Field Testing process in a future testing offering
  + If it is found that these data items are not readily available, then they will be tabled until a further time as needed
* Feasibility (Proposed SSDIs): For these data items, it has been determined that the information is available, and we are now testing the proposed codes/coding instructions
  + For these data items, registrars will be reviewing the proposed codes and coding instructions using real cases collected from registries
  + Once the study is over, the frequency distribution of answers and comments received, will be reviewed to determine if any changes need to be made to the data item prior to planned implementation
  + After these update are finalized, these data items move to the MLTG group for final approval

The 2021 Field Test

The 2021 Field Testing will be open November 1-December 15, 2021 and includes the following.

1. **Group 1:** Proposed SSDIs (Feasibility Testing): For these proposed SSDIs, you will have access to modified medical records, and the draft codes/coding instructions. This group also includes testing proposed changes to the Melanoma Skin primary site surgery codes.
   1. Primary Tumor Location (Brain, CNS Other and Intracranial Gland Schemas)
      1. ***Note: For purposes of the Field Testing****,* ***date of diagnosis is not relevant, please record the information regardless of whether it’s a new diagnosis, recurrence or progression***

*Note: For this proposed SSDI, there will be 4 cases per group*

* *Five groups of these cases are available. Only one group is required to complete a set of data items for CEUs*
  1. Primary Site Surgery Codes (Melanoma Skin Schema) (proposed changes)
     1. ***Note: For purposes of the Field Testing, code each surgical procedure. There will be three fields available to code surgical procedures. If there is not a second or third procedure, code “not applicable.”***

*Note: For this data item, there will be 2 cases per group*

* *Five groups of these cases are available. Only one group is required to complete a set of data items for CEUs*
  1. Margin Measurement (Melanoma Skin Schema)

*Note: For this proposed SSDI, there will be 2 cases per group*

* *Five groups of these cases are available. Only one group is required to complete a set of data items for CEUs*

1. **Group 2:** Proposed SSDIs (Feasibility Testing): For these proposed SSDIs, you will have 5 mini case scenarios with multiple choice questions, and the draft codes/coding instructions
   1. Histology Subtype (Appendix schema)
      1. *Note: This proposed SSDI will be looking at low-grade mucinous neoplasm (LAMN), high-grade mucinous neoplasm (HAMN) and other terminology assigned to ICD-O-3 code 8480****. For purposes of the Field Testing, LAMN is reportable***
         1. LAMN becomes reportable 1/1/2022

*Note: For this proposed SSDI, the case scenarios will be the same for all participants.*

1. **Group 3:** Potential SSDIs (Accessibility Testing): For these potential SSDIs, there will be a series of questions to answers about the frequency and availability of these clinical indicators. Please provide as much information as you can
   1. p16 (Anus schema)
   2. PD-L1 (Lung schema)
   3. PD-L1 (Melanoma Skin schema)
   4. HER2 (Colon and Rectum schema)

*Note: For each of these potential SSDIs, the questions will be the same for all participants.*

Estimated time to complete these data items is 2-3 hours

* If you would like to participate, but are unable to complete an entire set of cases, do as much as you can; however, you will not receive CEUs (partial credit not given)

General Instructions

The preferred answers and rationales were determined by a panel and are available for all the proposed SSDIs. They will be available to you on this site after you complete each case. You will also have the opportunity to comment on the data items and coding instructions as your feedback is important to this process. Since this is not a test for accuracy, individual participant results will remain confidential.

For each of the proposed SSDIs, you may key your answer in the corresponding box or select from the drop-down pick-list. Either mechanism works. For the potential SSDIs, answer as many of the questions that you can. You will be asked to complete demographic questions prior to beginning of the cases and a post study-participant poll after completing the cases.

3 CEUs will be awarded for completion of one group of cases, which includes:

* Primary Tumor Location (one set of 4 cases)
* Histology Subtype (5 multiple choice questions)
* Primary Site Surgery Codes (one set of 2 cases)
* Margin Measurement (one set of 2 cases)
* Answering at least one question for the following potential SSDIs: p16 (Anus), PD-L1 (Lung), PD-L1 (Melanoma Skin), HER2 (Colon and Rectum)

Registrars can earn up to 4 additional CEUs by completing up to 4 more groups of Primary Tumor Location, Primary Site Surgery Codes/Clinical Surgical Margins cases

* 4 cases per group for Primary Tumor Location and 2 cases per group for Primary Surgery Codes/Margin Measurement, 1 additional CEU awarded for each additional group completed

Practice cases are not available for the Field-Testing

Thank you for your participation in this important study!