NQF Measure Incubator® Request for Information: Oncology Measure Testing

Introduction

As the second leading cause of death in the U.S., cancer will touch nearly half of men and one-third of women in their lifetime. The physical, emotional, and economic impact of cancer is well-documented. Screening and treatment advances are showing progress in improving outcomes, extending survival rates, and reducing treatment side effects. Performance measures on quantity (survival) and patient-reported quality of life will address gaps in oncology measurement and may lead to improved quality of care for patients living with or at risk for cancer.

Working through the Measure Incubator®, an innovative effort that facilitates efficient measure development and testing through collaboration and partnership, National Quality Forum (NQF) is working to address these gaps. In 2017 and 2018, NQF, with support from Bristol-Myers Squibb, convened three oncology-focused strategy sessions. The first two strategy sessions, held in late 2017, focused on melanoma and lung cancer survival rates. At both meetings, expert panelists emphasized the importance of measuring survival within the context of quality of life, particularly among patients with advanced disease. A third strategy session held in 2018 explored patient-reported outcome performance measures (PRO-PM) for lung cancer. Expert panelists included patients, patient advocates, specialty society representatives, measure developers, health services researchers, and oncologists. The panelists identified a mix of measure concepts to assess survival rates, improve health-related quality of life, manage treatment side effects, and promote goal-concordant care and shared decision making.

Four measures were prioritized for initial development and testing under this project:

1. **Overall Survival for Small Cell Lung Cancer (SCLC):** Overall survival rate for patients with SCLC, with results stratified by stage
2. **Overall Survival for Non-Small Cell Lung Cancer (NSCLC):** Overall survival rate for patients with NSCLC, with results stratified by stage
3. **Overall Survival for Melanoma:** Overall survival rate for patients with melanoma, with results stratified by stage
4. **Patient Reported Symptom Burden Among NSCLC Patients Receiving Chemotherapy:** This PRO-PM assesses symptom burden during chemotherapy administered to adult patients with non-small cell lung cancer (NSCLC). Performance score for the measure is derived from:
    - patient-reported survey data (collected via an existing, validated survey instrument) administered during chemotherapy, and
    - clinical and demographic data collected for all eligible patients

Through the NQF Measure Incubator, work is underway to transform these measure concepts into fully specified and tested measures. Initial measure development (i.e., work to further refine the measure concepts, prepare pre-testing specifications, and compile expert recommendations) was

completed by Kristen McNiff of KM Healthcare Consulting in late 2018 and early 2019 (**see Appendix**). The Measure Incubator is now soliciting information from measure developers interested in testing the four specified measure concepts listed above (**see Appendix for pre-testing measure specifications)**.

This request for information (RFI) describes the measure concepts to be tested and the information that interested measure developers should provide to NQF. **NQF encourages innovative approaches to measure testing that promote efficiencies in the processes and associated budget. These do not necessarily have to follow traditional blueprints for measure testing. We strongly prefer and will prioritize measure developers that tackle all four measures but will consider proposals for testing of fewer measures.**

Project Overview

The NQF Measure Incubator seeks to identify an organization with proven experience in developing and testing healthcare performance measures (particularly in oncology-focused measures, outcomes, and PRO-PMs) to serve as the primary measure developer for the following measure concepts: 1) Overall Survival for Small Cell Lung Cancer; 2) Overall Survival for Non-Small Cell Lung Cancer; 3) Overall Survival for Melanoma; and, 4) Patient Reported Symptom Burden Among NSCLC Patients Receiving Chemotherapy (**see Appendix for pre-testing measure specifications**). Each concept requires testing (i.e., feasibility, reliability, and validity testing with risk adjustment/stratification, as appropriate) to produce finalized measures that are evidence-based and determined to be feasible, reliable, and valid. Measure testing should also explore questions identified during the development phase (e.g., minimum N for accountability).

The measure developer will lead testing of these concepts (including evaluating proposed stratification and risk adjustment, where appropriate) using a process that is cost-effective and efficient; novel testing approaches are encouraged.

Roles and Responsibilities

NQF Measure Incubator® (Facilitator)

The NQF Measure Incubator® brings together the necessary resources—such as measure development experts, clinicians, patients, data sources, and funding—to spur development of needed measures. In its role as project convener, the Measure Incubator will facilitate measure development and testing by others. NQF does not develop measures and will not be involved in day-to-day measure development and testing activities. The Measure Incubator will coordinate monthly calls with the measure developer(s)—and data partner(s), if necessary—to facilitate the work and provide suggestions and opportunities for efficiencies based on other Measure Incubator projects. However, the Measure Incubator will not enter into contractual agreements with data vendors, test sites, or any other partners engaged in the project.

Bristol-Myers Squibb (Funder)

In its role as project funder, Bristol-Myers Squibb will not engage directly with the measure developer, data partner(s), and/or potential test sites, nor will it specify or influence the outcome or processes of measure development and testing, in accordance with NQF Measure Incubator® COI principles.

Scope of Work

The measure developer will be responsible for the following tasks:

- Task 1: Solicit expert input to inform measure testing

  Note: The measure developer will have access to experts from the NQF-convened strategy sessions where the measure concepts were proposed, and NQF will assist in the identification of additional experts, as needed. However, NQF will not convene experts on behalf of the developer. The developer is encouraged to propose novel ways to integrate expert input into the process outside of the typical Technical Expert Panel process.
- Task 2: Identify and secure appropriate data partner(s) and/or test site(s)
  Note: The measure developer will be responsible for identifying and securing the appropriate data source(s) and test beds. The measure developer should identify how the data partner(s) and/or test site(s) can be utilized throughout the testing process. The measure developer will enter into contractual agreements with data vendor(s) and test site(s), as needed.
- Task 3: Develop and execute a detailed measure testing plan (with timeline and quality assurance protocols) to demonstrate the feasibility, reliability, and validity for each measure (including stratification and/or risk adjustment). Describe coordination of testing of all four measures, if proposing to test all four measures.
- Task 4: Provide monthly project status updates, including work completed and in progress, problems experienced and proposed solution(s), and upcoming activities.
- Task 5: Summarize measure testing results, including final measure specifications and risk stratification/risk adjustment methodology, in a final report for each measure.

Deliverables

The measure developer will be responsible for producing the following deliverables throughout the project's lifecycle:

- Task 2: Identify and secure appropriate data partner(s) and/or test site(s)
- Task 3: Detailed measure testing plan (with timeline and quality assurance protocols)
- Task 4: Written monthly project status updates
- Task 5: Four fully specified and tested performance measures on survival for SCLC, NSCLC, and melanoma as well as patient reported symptom burden among NSCLC patients receiving chemotherapy
- Task 5: Complete final report for each measure with measure specifications, stratification methodology, detailed feasibility, reliability, and validity testing results, and recommendations for implementation and further refinement

Estimated Measure Testing Timeline

The measure developer should create a timeline outlining the estimated time by task for measure testing.

Estimated Measure Testing Budget

The measure developer should provide a fixed fee budget outlining the costs (and expenses) by task with justification.

Minimum Qualifications of Key Personnel

Staff identified to be a part of the developer project team should include one or more methodologists, project managers, statisticians, data analysts, quality improvement experts, and subject matter experts in oncology. The key personnel should be able to demonstrate the following qualifications:

- Established track record for successful evidence-based measure development, including cancer-specific measures, outcomes, and PRO-PMs
- Substantial experience with all aspects of design and execution for measure development and testing, including scientific evidence review, measure specification and testing (for feasibility, reliability, and validity), data analysis, risk adjustment (including clinical and social risk factors), and report writing
- Depth and breadth of relevant expertise, such as clinical practice, measurement methodology, health services research and/or epidemiology, clinical informatics, professional and technical claims coding, statistics, quality improvement, electronic health record (EHR) data systems and workflows, other healthcare data sources (including claims and registries), quantitative and qualitative data analysis, programming, and technical writing
- Strong project management skills, including the ability to manage accelerated and overlapping timelines
- Familiarity with NQF measure evaluation criteria

  Note: In accordance with NQF Measure Incubator® COI principles, incubated measures are conferred no advantage in the NQF endorsement process, nor is pursuit of NQF endorsement a requirement for incubated measures.

Measure developers may contract with outside individuals or organizations to ensure that the project team has the necessary expertise to support this project.

RFI Requirements

The measure developer should include the following information in the response:

- **High-level work plan outlining measure testing activities** (including feasibility, reliability, and validity testing and risk stratification (or risk adjustment) methodology, as appropriate)

  Note: The work plan should address the methods, processes, procedures, and protocols necessary for effective and efficient completion of all measure testing activities and associated deliverables. There should be enough description that Measure Incubator® staff can evaluate the appropriateness and sufficiency of the proposed testing methods.
- **Project timeline with key milestones and dates**

  Note: At a minimum, the proposed project timeline should include each task, with key milestones and dates.
- **Summary-level budget**

  Note: At a minimum, the proposed fixed fee budget should include estimated hours, fees, and expenses for each task.
- For each task, the **staffing and management roles and responsibilities** (including contracted resources). Please provide resumes or curriculum vitae for key personnel, which demonstrate specific experience with measure development and validation (including cancer-specific measures, outcomes, and PRO-PMs)
- **Measure development and project management capabilities** (including examples of

previous measure development and references), specifying which capabilities are in-house and which capabilities would be outsourced

Responses to the scope of work should be no more than 10 pages in length (excluding resumes and references).

Evaluation of the Responses

Responses will be evaluated based on the following criteria:

- Overall Suitability: Proposed testing approach(es) must meet the scope and needs outlined above and be presented in a clear and organized manner.
- Value and Cost: Respondents will be evaluated on the timeline and cost of their approach(es) based on the work to be performed in accordance with the scope of this project.
- Past Experience/Qualifications: Respondents will be evaluated based on their experience as it pertains to the scope of this project. Respondents must provide descriptions and documentation of assigned key personnel's technical expertise and experience.
- Novelty and Efficiency: Proposed testing approach(es) will be evaluated for their novelty and ability to provide efficient and cost-effective measure testing.

Submission Instructions

Responses should be submitted via email to incubator@qualityforum.org by 5:00pm Eastern on July 31, 2019.

Please direct any questions regarding the RFI to incubator@qualityforum.org.

Appendix: NQF Measure Incubator® Cancer Outcome Measure Panels: Pre-Testing Specification Report Prepared by: Kristen McNiff, KM Healthcare Consulting

NQF Measure Incubator® convened expert panels to discuss and prioritize outcome measures for small cell lung cancer (September 2017); melanoma (October 2017); and non-small cell lung cancer (April 2018). Kristen McNiff of KM Healthcare Consulting was engaged to further refine the measure concepts; prepare pre-testing specifications; and compile expert recommendations.

Section 1. Lung Cancer and Melanoma Survival Measures

Based on the NQF Measure Incubator® panel discussions, and review of the project environmental scan/published guidelines/literature, indicator description templates were created for non-small cell lung cancer survival, small cell lung cancer survival, and melanoma survival. The indicator templates were created to gather structured guidance and feedback from the expert panelists attending each of the panel meetings, as the agenda (which covered multiple outcome measure types) and duration of those meetings did not permit detailed discussion. To minimize burden and seek to maximize response, the indicator templates were structured to allow for electronic completion. They included questions and clarifications for most specification components (see Appendix A). Per discussion with Tracy Spinks, the SCLC and NSCLC templates were combined into one document for review and response by both panels.

The templates were distributed via email to all panel members in November 2018. Panelists received three email reminders (two prior to the due date; one following, for those who had not responded). Those who did not respond were offered the opportunity to convene on a 1:1 webinar for a facilitated review of the document. Three panelists who had not responded electronically agreed to complete the template via webinar.

All template responses were collected and compiled to identify areas of consensus and themes. The indicator specification templates were refined accordingly. It should be noted, however, that none of the major specification questions were fully addressed by responses from the panelists. As such, these questions were retained for the subsequent phase of review: individual interviews with clinicians with lung cancer expertise and melanoma expertise.

Experts who had not been involved in the NQF panels were solicited, including through outreach to the Alliance of Dedicated Cancer Centers (ADCC) for nominations. Nine lung cancer experts and 6 melanoma experts were recommended and accepted the request to participate. Ultimately, due to scheduling challenges, interviews were completed with 7 lung cancer experts and 5 melanoma experts. Modified indicator templates were distributed for review in advance and were used to record expert feedback.

Interviews took 45 to 90 minutes to complete; most lung interviews also included discussion of the proposed PRO-PM measure (see below). Experts participating in the interviews demonstrated consensus related to many of the open specification questions. There were

challenges in fully defining specifications due to the fact that the measure testing/implementation data source is unknown. Most experts also shared overall recommendations for consideration prior to and during testing. These recommendations were noted.

Pre-testing specifications resulting from this phase of work are included below. Where a lack of consensus/clarity remained (often due to uncertainty about the data source), this is noted. It is clear that the specifications will require refinement once the testing data source is identified. Themes related to the specification review included:

- Inclusion of all stages: Overall, respondents identified challenges with including all stages in the lung and melanoma measures. They understood the concept of stratifying the results, but the general sense was that this is most appropriate for surveillance. Narrowing the survival measure denominators might allow for more understandable/meaningful and precise measures. This might be considered during testing. Further, inclusion of all stages especially presented challenges related to attribution. Respondents generally replied that the providers most active in and responsible for the patient outcomes differed based on the stage. Further, many respondents felt that attribution to a single facility providing the majority of care was most appropriate for advanced patients, but that those with earlier stage disease should be attributed to multiple facilities, if relevant, based on plurality of care rules.
    - Melanoma experts provided consistent feedback that a melanoma measure should not include all stages, even for testing. **Melanoma experts consistently suggested limiting the measure to advanced or metastatic melanoma.**
- Survival measurement: Most respondents (panelists and interviewed experts) considered 'percent alive' to be more understandable and feasible than a survival rate based on a hazard ratio. Most notably, respondents overall and patient representatives specifically did not think that survival reported as a HR is meaningful to patients. However, there was interest in also testing a HR-based measure if the data source would allow.
- Minimum N for accountability: the consensus of the respondents is documented in specifications; however, they agreed that the minimum N should be empirically tested using appropriate statistical techniques during measure testing.

Finally, a few broad themes and recommendations emerged from the experts. Although these areas were not the main focus of the NQF Measure Incubator® project, **the experts demonstrated overall enthusiasm for engagement in the following areas to meaningfully contribute to cancer survival measurement:**

1. Cancer survival measurement is consistently challenged by **small Ns.** This is exacerbated by the need to limit denominators or stratify by critical clinical factors such as stage. Small Ns are problematic for measurement at hospital/facility levels, and can prevent valid measurement at practice and provider levels altogether. A recommendation emerging from this work is to conduct a testing process/analysis focused specifically on this issue. Such an effort would entail identifying a minimum N at the unit of analysis

(e.g., via a modified power calculation), and then creating specification decisions that are clinically appropriate/meaningful and allow the sample size to be met (in effect, reversing the order of a standard specification process). A robust data set would be required to allow for empirical testing of various decision paths in order to identify all specification components, including attribution approach/rules and denominator inclusion/exclusion.

2. Cancer survival measurement is also consistently challenged by appropriate attribution rules, as cancer care generally requires multiple specialties and is usually conducted at multiple sites of care. There was enthusiasm across the experts for **measuring survival at the 'team' level**; yet, no methodology or analytic approach exists to do so. A recommendation from this work is to empirically define a 'team' that can be used in cancer survival (and other outcome) measurement. With the emergence of ACOs and increasing focus on population health management, there is a growing acceptance of a shared accountability across providers practicing within different settings. Experts felt that the NQF Measure Incubator could contribute by facilitating efforts to analytically define the key providers involved in a patient's care, allowing for 'team' based measurement, rather than current state reliance on Tax ID Number (TIN) or National Provider Identifier (NPI) based measurement.

Measure 1. Pre-Testing Specifications: Overall Survival for Small Cell Lung Cancer (SCLC)

- Brief Description: Overall survival rate for patients with SCLC, with results stratified by stage

- Timing of measure initiation: From time of diagnosis

- Timing of measure calculation: 2-year and 5-year survival for AJCC stages I-III/limited stage; 1-year and 2-year survival for AJCC stage IV/extensive stage

- Denominator:
    - Adult patients with a SCLC diagnosis within the measurement period
        - Note: patients included in the analysis will be those with sufficient elapsed time between diagnosis and measurement time-point

- Denominator exclusions:
    - More than one cancer diagnosis (excluding in-situ cancers, non-melanoma skin cancers, and non-metastatic prostate cancer) within the measurement period
    - Previous cancer diagnosis (excluding in-situ cancers, non-melanoma skin cancers, and non-metastatic prostate cancer) in past 5 years
        - Alternative, if data exists: Treatment for another cancer diagnosis received in past 5 years

    - Note: respondents were split regarding whether patient declining treatment should be an exclusion. Many raised questions regarding whether the data source will reliably capture this information, and others commented that the quality of communication regarding treatment options will impact this exclusion. Certain experts noted that this exclusion might be required to achieve NQF endorsement. Ultimately, if the data source supports including this as an exclusion for testing, careful evaluation of this exclusion is recommended.

- Numerator: Percent of patients alive at the defined time-points (2 years and 5 years for stages I-III/limited stage; 1 year and 2 years for stage IV/extensive stage)

- Stratification:
    - Stratify by AJCC stage at diagnosis (I, II, III, IV). If Ns are insufficient at this level, then:
    - Stratify by limited vs extensive disease at diagnosis
        - Limited stage (I-III), excluding T3-T4 due to multiple lung nodes
        - Extensive stage (IV), or T3-T4 due to multiple lung nodes

  - Note: patients should remain in the stratification category based on stage at diagnosis. Progression and survival after progression should be evaluated as distinct outcomes.

- Risk Adjustment: Covariates for testing identified are:
  - Age
  - Sex
  - Race
  - Ethnicity
  - Education level
  - Insurance status
  - Income (household)
  - Weight loss (more than 5% of actual weight in previous 6 months)
  - CNS involvement at diagnosis
  - Comorbidities (modified Kabunde suggested)
  - Add kidney function if not adequately captured in comorbidities
  - Smoking status (former/ current)
  - Performance status (ECOG/Karnofsky)
  - Elevated lactate dehydrogenase (LDH)
  - Global health status/quality of life (if available)
  - Geographic region of US

  - Note: the testing analysis should assess outcome differences by hospital/facility factors (e.g., academic/tertiary vs community vs private practice), but the measure should not be risk adjusted based on those factors

- Accountability/Attribution:
  - Hospitals and private oncology practices should be the unit of measurement and accountability
  - Note: respondents generally supported using 'teams' as a meaningful unit of analysis, but universally noted the challenge in identifying a 'team' within the fragmented health care/cancer care system. Several recommended testing oncology 'team' definitions for measurement based on those most involved in a patient's care, rather than using a TIN definition (see recommendation).
  - Note: There was lack of consensus regarding whether and which individual providers should be held accountable. The inclusion of limited and advanced stages made this especially challenging as the relative impact of specialists on survival differs based on stage.

  - A slight majority of respondents favored attribution to only one healthcare entity, which provided the majority of SCLC care (>50%) measured by visits/claims. This option was mostly favored for advanced disease.

  - Also supported was attribution to multiple healthcare entities (e.g., multiple hospitals), based on plurality of SCLC care (e.g., >30%). This option was mostly favored for limited disease.

- Minimum Number for QI: for internal quality improvement, experts recommended reporting any number of patients (no minimum). If comparison data will be provided in quality measure reporting, most respondents recommended 20 per measurement period.
- Minimum Number for Accountability: Respondents noted this as a key issue (see recommendations). A minimum of 30 was suggested, but most respondents agreed that the minimum number should be evaluated empirically during testing.

Measure 2: Overall Survival for Non-Small Cell Lung Cancer (NSCLC)

- Brief Description: Overall survival rate for patients with NSCLC, with results stratified by stage

- Timing of measure initiation: From time of diagnosis

- Timing of measure calculation: 5-year survival for AJCC stage I-II; 2-year survival for AJCC stage III; 1- and 2-year survival for AJCC stage IV

- Denominator:
    - Adult patients with a NSCLC diagnosis within the measurement period
        - Note: patients included in the analysis will be those with sufficient elapsed time between diagnosis and measurement time-point

- Denominator exclusions:
    - More than one cancer diagnosis (excluding in-situ cancers, non-melanoma skin cancers, and non-metastatic prostate cancer) within the measurement period
    - Previous cancer diagnosis (excluding in-situ cancers, non-melanoma skin cancers, and non-metastatic prostate cancer) in past 5 years
        - Alternative, if data exists: Treatment for another cancer diagnosis received in past 5 years

    - Note: respondents were split regarding whether patient declining treatment should be an exclusion. Many raised questions regarding whether the data source will reliably capture this information, and others commented that the quality of communication regarding treatment options will impact this exclusion. Certain experts noted that this exclusion might be required to achieve NQF endorsement. Ultimately, if the data source supports including this as an exclusion for testing, careful evaluation of this exclusion is recommended.

- Numerator: Percent alive within the defined time-points (5 years for stage I-II; 2 years for stage III; 1 and 2 years for stage IV)

- Stratification:
    - Stratify by stage at diagnosis (I, II, III, IV). If Ns are insufficient at this level, then:
    - Stratify by early stage vs locally advanced vs advanced/metastatic disease at diagnosis:
        - Early stage (stage I, selected node negative IIA)
        - Locally advanced (stages II-III)
        - Advanced/metastatic (stage IV)

  - Note: patients should remain in the stratification category based on stage at diagnosis. Progression and survival after progression should be evaluated as distinct outcomes.

- Risk Adjustment:
  - Age
  - Sex
  - Race
  - Ethnicity
  - Education level
  - Insurance status
  - Income (household)
  - Weight loss (more than 5% of actual weight in previous 6 months)
  - CNS involvement at diagnosis
  - Comorbidities (modified Kabunde suggested)
    - Add kidney function if not adequately captured in comorbidities
  - Smoking status (past and current)
  - Performance status (ECOG/Karnofsky)
  - Histology
  - Elevated LDH
  - ALK status
  - EGFR status
  - ROS1 status
  - BRAF status
  - PDL1 expression
  - Global health status/quality of life (if available)
  - Geographic region of US

  - Note: the testing analysis should assess outcome differences by hospital/facility factors (e.g., academic/tertiary vs community vs private practice), but the measure should not be risk adjusted based on those factors

- Accountability/Attribution:
  - Hospitals and private oncology practices should be the unit of measurement and accountability
  - Note: respondents generally supported using 'teams' as a meaningful unit of analysis, but universally noted the challenge in identifying a 'team' within the fragmented health care /cancer care system. Several recommended testing oncology 'team' definitions for measurement based on those most involved in a patient's care, rather than using a TIN definition (see recommendation).
  - Note: There was lack of consensus regarding whether and which individual providers should be held accountable. The inclusion of limited and advanced stages made this especially challenging as the relative impact of specialists on survival differs based on stage.

  - A slight majority of respondents favored attribution to only one healthcare entity, which provided the majority of NSCLC care (>50%) measured by visits/claims. This option was mostly favored for advanced disease.
  - Also supported was attribution to multiple healthcare entities (e.g., multiple hospitals), based on plurality of NSCLC care (e.g., >30%). This option was mostly favored for limited disease.

- Minimum Number for QI: for internal quality improvement, experts recommended reporting any number of patients (no minimum). If comparison data will be provided in quality measure reporting, most respondents recommended 20 per measurement period.
- Minimum Number for Accountability: Respondents noted this as a key issue (see recommendations). A minimum of 30 was suggested, but most respondents agreed that the minimum number should be evaluated empirically during testing.

Measure 3. Overall Survival for Melanoma

- Brief Description: Overall survival rate for patients with melanoma, with results stratified by stage
- Note: Melanoma experts provided consistent feedback that a melanoma measure should not include all stages, even for testing. **Melanoma experts consistently suggested limiting the measure to advanced or metastatic melanoma (with stratification for stage IV at diagnosis and progression).**

- Timing of measure initiation: From time of diagnosis

- Timing of measure calculation: 5-year survival for AJCC stages I-III, 2- and 3-year survival for AJCC stage IV/metastatic.

- Denominator:
    - Adult patients with a melanoma diagnosis within the measurement period
        - Note: as previously noted, respondents recommended limiting the denominator to metastatic disease

- Denominator exclusions:
    - More than one cancer diagnosis (excluding in-situ cancers, non-melanoma skin cancers, and non-metastatic prostate cancer) within the measurement period
    - Previous cancer diagnosis (excluding in-situ cancers, non-melanoma skin cancers, and non-metastatic prostate cancer) in past 5 years
        - Alternative, if data exists: Treatment for another cancer diagnosis received in past 5 years

    - Note: respondents were split regarding whether patient declining treatment should be an exclusion. Many raised questions regarding whether the data source will reliably capture this information, and others commented that the quality of communication regarding treatment options will impact this exclusion. Certain experts noted that this exclusion might be required to achieve NQF endorsement. Ultimately, if the data source supports including this as an exclusion for testing, careful evaluation of this exclusion is recommended.

- Numerator: Percent alive within the defined time-points (5 years for stages I-III, 2 and 3 year for metastatic)

- Stratification:
    - If all stages are included, stratify by stage at diagnosis (I, II, III, IV)
    - If the denominator is limited to metastatic melanoma, stratify by stage IV at diagnosis and progression to metastatic disease.

- Risk Adjustment:
    - Age
    - Sex
    - Race
    - Ethnicity
    - Education level
    - Insurance status
    - Income
    - Functional status
    - Comorbidity score
    - Body region/primary tumor site
    - Brain metastases
    - BRAF mutation status
    - KIT mutation status
    - Elevated lactate dehydrogenase (LDH)
    - Global health status/quality of life (if available)
    - Geographic region of US

    - Note: the testing analysis should assess outcome differences by hospital/facility factors (e.g., academic/tertiary vs community vs private practice), but the measure should not be risk adjusted based on those factors

- Accountability/Attribution:
    - Hospitals should be the unit of measurement and accountability
    - Note: respondents were split on the appropriateness of attribution to private oncology practices for melanoma survival. There was general consensus that individual providers should not be held accountable.
    - Note: respondents generally supported using 'teams' as a meaningful unit of analysis, but universally noted the challenge in identifying a 'team' within the fragmented health care /cancer care system. Several recommended testing oncology 'team' definitions for measurement based on those most involved in a patient's care, rather than using a TIN definition (see recommendation).

    - A slight majority of respondents favored attribution to only one healthcare entity, which provided the majority of melanoma care (>50%) measured by visits/claims. This option was mostly favored for advanced disease.
    - Also supported was attribution to multiple healthcare entities (e.g., multiple hospitals), based on plurality of melanoma care (e.g., >30%). This option was mostly favored for limited disease.

- Minimum Number for QI: for internal quality improvement, experts recommended reporting any number of patients (no minimum). If comparison data will be provided in quality measure reporting, most respondents recommended 20 per measurement period.

- Minimum Number for Accountability: Respondents noted this as a key issue (see recommendations). A minimum of 30 was suggested, but most respondents agreed that the minimum number should be evaluated empirically during testing.

Section 2. NSCLC Lung Cancer Patient-Reported Outcome Performance Measure (PRO-PM)

The collection of feedback and guidance for pre-testing specification of the NSCLC PRO-PM was completed via the process described above for the lung cancer survival measures. A PRO-PM feedback document was prepared to collect responses from panelists. The experts participating in 1:1 interviews responded to open-ended questions, with responses recorded.

Based on output from the NQF Measure Incubator panel, a PRO-PM including all NSCLC stages was proposed, categorized according to the following definitions (source: NCCN):

- Early stage (stage I, selected node negative IIA)
- Locally advanced (stages II-III)
- Advanced/metastatic (stage IV)

However, respondents did not support a measure including all NSCLC stages, as they did not think the resulting performance scores would be meaningful. Advanced/metastatic NSCLC and locally advanced NSCLC were prioritized.

Other key feedback areas and recommendations:

- To accelerate PROM testing, a test site/test sites with existing PRO data should be identified as long as that site meets minimum requirements (see below)
- Rather than select a specific PROM, allow use of any of the major validated instruments (e.g., those identified in the panel materials and/or ICHOM report) that has been selected by the test site and includes the prioritized symptoms:
    - Pain
    - Cough
    - Dyspnea
    - Appetite
    - Nausea/Vomiting
    - Diarrhea
    - Constipation
    - Fatigue/sleep disturbance

Similar to the panel discussion, experts who provided feedback considered symptom burden to be an important patient-centered outcome with further clinically importance due to associated treatment modifications. To allow overall assessment in this area, the following related measures were suggested for consideration:

1. Symptom burden among NSCLC patients receiving chemotherapy
    a. Process measure: Percentage of NSCLC patients with symptoms assessed
2. Symptom burden among NSCLC patients receiving radiation therapy
    a. Process measure: Percentage of NSCLC patients with symptoms assessed
3. Percentage of patients with symptom-related treatment modification

Among the symptom burden measures, measurement during both systemic and radiation therapies were supported, with priority for measurement during chemotherapy.

The process measure, percentage of NSCLC patients with symptoms assessed, was recommended to ensure that reliability and bias issues can be identified. The recommendation is that the completion rate required for calculation of the PRO-PM be empirically defined from testing data. The process measure is also considered important as routine PROM collection is not standard of care.

The measure 'Percentage of patients with symptom-related treatment modifications' was recommended as an alternate or companion to the PRO-PM; however, participants noted the challenges in identifying dose modifications, treatment plan changes, treatment stoppage due to AEs, etc.

The remainder of this pre-testing specification document focuses on the PRO-PM: Symptom burden among NSCLC patients receiving chemotherapy.

Various numerator calculations are possible for this measure, and are in part dependent on the selected instrument. The pre-testing recommendation is to measure moderate to high symptom burden, present on more than one survey response. A second proposed numerator to test, if supported by the PROM, is symptom interference. (See Specification Summary); however, validated PROMs do not support this approach for the prioritized outcomes.

The frequency and timing of survey administration should ensure that sufficient data points are available to assess the numerator. There is not an evidence base for timing; however, to meet the goals of the measure, it is suggested that the surveys be administered at every visit or monthly at minimum during the course of chemotherapy administration.

PRE-TESTING MEASURE SPECIFICATION SUMMARY

Measure Title:

Patient Reported Symptom Burden among NSCLC Patients Receiving Chemotherapy

Brief Rationale:

Early detection of treatment side effects is important to determine optimal dosing and mitigate treatment breaks and delays. Optimal care involves driving toward the treatment with the highest efficacy and lowest toxicity. Furthermore, routine assessment helps facilitate patient/provider communication regarding symptom exacerbation

Brief Description:

This PRO-PM assesses symptom burden during chemotherapy administered to adult patients with non-small cell lung cancer (NSCLC). Performance score for the measure is derived from:

- patient-reported survey data (collected via an existing, validated survey instrument) administered during chemotherapy, and
- clinical and demographic data collected for all eligible patients

The measurement unit of analysis for testing is the medical oncology practice or hospital-based medical oncology.

Numerator Statement:

- Moderate to high symptom burden during chemotherapy

The measure numerator will be calculated from aggregated, patient-level scores from the PROM administrations during chemotherapy. 'Moderate to high' – or similar terms of severity – may be defined during psychometric testing of the selected instrument. Severity level may be determined for a summary symptom scale, if supported by the instrument.

- **PRO survey instrument**: TBD. A PROM which assesses each of the prioritized symptoms (pain, cough, dyspnea, appetite, nausea/vomiting, diarrhea, constipation, fatigue/sleep disturbance), and which has been validated in NSCLC patients. A PROM with cross-walks to other instruments is ideal.

Denominator Statement:

Patients over age 18 with stages II-IV NSCLC, AND receiving chemotherapy

Note: testing sites/data sources should be used to determine whether patients who progress to metastatic disease are included. If not, progression will be a measure exclusion and the denominator can be limited to patients receiving an initial chemotherapy regimen. If included, metastatic due to disease progression should be tested as a distinct stratification category.

Note: depending on how survey response requirements will be handled (see introductory text), the denominator and exclusions will be impacted. Potential survey-related exclusions:

- *surveys not administered/not administered within time window*
- *patient refusal to complete surveys (define based on minimum number)*

- *missing data prevents survey analysis (define based on minimum)*

Denominator Exclusions:

- patients with 2 or more concurrent cancer diagnoses (other than non-melanoma skin cancer)
- patients who previously received chemotherapy for the same cancer
- concurrent chemotherapy and radiation treatment for NSCLC patients
- patients with recurrence of disease
- patients with disease progression or metastatic cancer
- patients on clinical trials

Stratification:

The measures will be stratified by

- Locally advanced (stages II-III)
- Advanced/metastatic (stage IV)

Risk Adjustment:

Risk adjustment variables to be tested will include clinical factors, cancer factors, demographics, and treatment history. *Note: testing site data availability should be assessed for final covariate selection.*

- Age
- Sex
- Race
- Ethnicity
- Education level
- Insurance status
- Income
- Weight loss (more than 5% of actual weight in previous 6 months)
- CNS involvement at diagnosis
- Comorbidity score
- Smoking status
- Performance status (ECOG/Karnofsky)
- Histology
- Time between diagnosis and treatment
- Chemotherapy regimen (categorical for symptom burden)
- Other systemic treatments (type, dates)
- Surgery (type, date)
- Radiation treatment (type, date)
- Mental health PROM items, if available
- Geographic region of US

APPENDIX A. TEMPLATE USED FOR PANELIST FEEDBACK DURING SPECIFICATION

Instructions to Panelists:
Below are draft specifications for the survival measure discussed during your panel meeting. Any comments are welcome, but please respond specifically to the Decision Items which are in red. Enter your responses in the highlighted areas.

Measure: Overall Survival for Small Cell Lung Cancer

- Brief Description: Overall survival rate for patients with SCLC, with results stratified by stage

- Timing of measure initiation:
  - ✓ Decision item 1. Please rank order the following options for the initiation of survival measurement
    - From time of diagnosis: [Enter rank 1, 2, 3]
    - From initiation of treatment: [Enter rank 1, 2, 3]
    - From completion of treatment: [Enter rank 1, 2, 3]
      - Please define 'treatment'. E.g., first treatment, regardless of type (surgery, systemic, radiation)? Other?: [Enter]

- Timing of measure calculation:
  - ✓ Decision item 2. What are the most meaningful timepoints for measuring SCLC survival (e.g., 1 year survival, 2 year survival, 5 year survival)? For those with limited stage? Extensive stage?
    - [Enter]

- Denominator:
  - Adult patients with a SCLC diagnosis within measurement period
    - Note: 'SCLC diagnosis' will be defined according to the data source
    - Note: patients included in the analysis will be those with sufficient elapsed time between diagnosis and measurement time-point

- Denominator exclusions: More than one cancer diagnosis within the measurement period
  - ✓ Decision item 3. Are there additional exclusions - any other cases where a patient should be removed from the analysis altogether?
    - [Enter]

- Numerator: Survival rate [within the defined time-points, above]
  - ✓ Decision item 4. What survival data are most meaningful? For example, hazard ratio with confidence intervals?

- [Enter]
- Note: data source that reliably captures death data is required

- Stratification: Survival rate will be stratified by stage categories
  - Note: the data source will dictate availability of staging information. If both clinical and pathological stage information is available, the combined AJCC stage group used by the NCDB can be considered.
  - ✓ Decision item 5. Should stratification be by each stage (I, II, III, IV), or should stratification be by limited stage and extensive stage? (More stratification categories will lead to smaller Ns, which can be problematic, but stratified results should be as meaningful as possible). Select your preference:
    - Stratify by stage at diagnosis (I, II, III, IV): [Enter if your preference]
    - Stratify by limited stage vs extensive stage at diagnosis: [Enter if your preference]
      - Please confirm the following definitions from NCCN guidelines, or provide an alternate definition:
      - Limited stage (I-III), excluding T3-T4 due to multiple lung nodes
      - Extensive stage (IV), or T3-T4 due to multiple lung nodes
        - [Enter confirmation of this definition or provide alternative]
    - Other suggestion for stratification? [ENTER]
  - ✓ Decision item 6. Should stratification separate patients who had limited stage disease at diagnosis, but then progressed to metastatic disease?
    - [Enter]

- Risk Adjustment:
  - ✓ Decision item 7. Please review the potential factors to test for risk adjustment. These should capture factors that impact survival, but are beyond the control of treating providers. Note: the data source for analysis may not provide all desired risk adjustment variables. At this point, identify risk adjustment variables which are desired. [Edit the list below – remove, add, modify risk adjustment variables]
    - Age
    - Sex
    - Race
    - Ethnicity
    - Education level
    - Insurance status
    - Income
    - Weight loss
    - Comorbidities (using standardized assessment)
    - Smoking status (historical and current)
    - Performance status (ECOG/Karnofsky)
    - Histology
    - Elevated lactate dehydrogenase (LDH)

- Hospital/facility factors [Enter specific factors if these should be tested for risk adjustment]
- Geographic region of US

- Accountability/Attribution:
  - ✓ Decision item 8. Considering your responses to the questions above, which provider type(s) should be held accountable for overall survival for SCLC (that is, what is the unit of measurement)?
    - Hospitals [Enter yes or no]
    - Private practices [Enter yes or no]
    - Individual oncologists [Enter yes or no]
  - ✓ Decision item 9. When attributing a patient to a provider to measure SCLC survival, which approach is preferred?
    - Each patient is attributed to only one provider (e.g., one hospital) [Enter yes or no]
    - Each patient can be attributed to multiple providers (e.g., multiple hospitals) if multiple providers were substantively involved in that patient's care [Enter yes or no]
  - ✓ Decision item 10. Please rank order the following specific approaches to attribute patients to measure SCLC survival.
    - Attribute patients to the provider (e.g., hospital) that provided the majority of SCLC care (>50%) [Enter rank 1 2 3 4]
    - Attribute patients to the provider (e.g., hospital) that billed the majority of costs for SCLC care (>50%) [Enter rank 1 2 3 4]
    - Attribute patients to the provider (e.g., hospital) that provided a specific treatment (e.g., the first systemic therapy) [Enter rank 1 2 3 4; enter comment re: which treatment]
    - Attribute patients to provider(s) that provided a plurality of SCLC care (e.g., >30%) [Enter rank 1 2 3 4]
    - Other approach: [Enter and rank]
  - ✓ Decision item 11. Indicate the minimum number of patients which should be attributed to a provider in order for the survival rate to be calculated for that provider. For example, if a provider has only 4 patients attributed during the measurement period, should a survival rate be calculated? What minimum number will allow for meaningful analysis?
    - [Enter minimum number if the data will only be used for internal QI]
    - [Enter minimum number if the data will be publicly reported]

Measure: Overall Survival for Non-Small Cell Lung Cancer (NSCLC)

- Brief Description: Overall survival rate for patients with NSCLC, with results stratified by stage

- Timing of measure initiation:
  - ✓ Decision item 1. Please rank order the following options for the initiation of survival measurement
    - From time of diagnosis: [Enter rank 1, 2, 3]
    - From initiation of treatment: [Enter rank 1, 2, 3]
    - From completion/discontinuation of treatment: [Enter rank 1, 2, 3]
      - Please define 'treatment'. E.g., first treatment, regardless of type (surgery, systemic, radiation)? Other?: [Enter]

- Timing of measure calculation:
  - ✓ Decision item 2. What are the most meaningful timepoints for measuring NSCLC survival(e.g., 1 year survival, 2 year survival, 5 year survival)? For those with early stage disease? Locally advanced disease? Advanced/metastatic disease?
    - [Enter]

- Denominator:
  - Adult patients with a NSCLC diagnosis within measurement period
    - Note: 'NSCLC diagnosis' will be defined according to the data source
    - Note: patients included in the analysis will be those with sufficient elapsed time between diagnosis and measurement time-point

- Denominator exclusions: More than one cancer diagnosis within the measurement period
  - ✓ Decision item 3. Are there additional exclusions - any other cases where a patient should be removed from the analysis altogether?
    - [Enter]

- Numerator: Survival rate [within the defined time-points, above]
  - ✓ Decision item 4. What survival data are most meaningful? For example, hazard ratio with confidence intervals?
    - [Enter]
  - Note: data source that reliably captures death data is required

- Stratification: Survival rate will be stratified by stage categories
  - Note: the data source will dictate availability of staging information. If both clinical and pathological stage information is available, the combined AJCC stage group used by the NCDB can be considered.
  - ✓ Decision item 5. Should stratification be by each stage (I, II, III, IV), or should stratification be by early stage vs locally advanced vs advanced/metastatic disease?

(More stratification categories will lead to smaller Ns, which can be problematic, but stratified results should be as meaningful as possible). Select your preference:

- Stratify by stage at diagnosis (I, II, III, IV): [Enter if your preference]
- Stratify by early stage vs locally advanced vs advanced/metastatic disease at diagnosis: [Enter if your preference]
  - Please confirm the following definitions from NCCN guidelines, or provide an alternate definition:
  - Early stage (stage I, selected node negative IIA)
  - Locally advanced (stages II-III)
  - Advanced/metastatic (stage IV)
    - [Enter confirmation of this definition or provide alternative]
- Other suggestion for stratification? [ENTER]

✓ Decision item 6. Should stratification separate patients who had non-metastatic disease at diagnosis, but then progressed to metastatic disease?

- [Enter]

- Risk Adjustment:
  - ✓ Decision item 7. Please review the potential factors to test for risk adjustment. These should capture factors that impact survival, but are beyond the control of treating providers. Note: the data source for analysis may not provide all desired risk adjustment variables. At this point, identify risk adjustment variables which are desired. [Edit the list below – remove, add, modify risk adjustment variables]
    - Age
    - Sex
    - Race
    - Ethnicity
    - Education level
    - Insurance status
    - Income
    - Weight loss
    - Comorbidities using standardized assessment
    - Smoking status (historical and current)
    - Performance status (ECOG/Karnofsky)
    - Histology
    - ALK status
    - EGFR status
    - ROS1 status
    - BRAF status
    - Hospital/facility factors [Enter specific factors if these should be tested for risk adjustment]
    - Geographic region of US

- Accountability/Attribution:

- ✓ Decision item 8. Considering your responses to the questions above, which provider type(s) should be held accountable for overall survival for NSCLC (that is, what is the unit of measurement)?
  - Hospitals [Enter yes or no]
  - Private practices [Enter yes or no]
  - Individual oncologists [Enter yes or no]
- ✓ Decision item 9. When attributing a patient to a provider to measure NSCLC survival, which approach is preferred?
  - Each patient is attributed to only one provider (e.g., one hospital) [Enter yes or no]
  - Each patient can be attributed to multiple providers (e.g., multiple hospitals) if multiple providers were substantively involved in that patient's care [Enter yes or no]
- ✓ Decision item 10. Please rank order the following specific approaches to attribute patients to measure NSCLC survival.
  - Attribute patients to the provider (e.g., hospital) that provided the majority of NSCLC care (>50%) [Enter rank 1 2 3 4]
  - Attribute patients to the provider (e.g., hospital) that billed the majority of costs for NSCLC care (>50%) [Enter rank 1 2 3 4]
  - Attribute patients to the provider (e.g., hospital) that provided a specific treatment (e.g., curative surgery or the first systemic therapy) [Enter rank 1 2 3 4; enter comment re: which treatment]
  - Attribute patients to provider(s) that provided a plurality of NSCLC care (e.g., >30%) [Enter rank 1 2 3 4]
  - Other approach: [Enter and rank]
- ✓ Decision item 11. Indicate the minimum number of patients which should be attributed to a provider in order for the survival rate to be calculated for that provider. For example, if a provider has only 4 patients attributed during the measurement period, should a survival rate be calculated? What minimum number will allow for meaningful analysis?
  - [Enter minimum number if the data will only be used for internal QI]
  - [Enter minimum number if the data will be publicly reported]

Measure: Overall Survival for Melanoma

- Brief Description: Overall survival rate for patients with melanoma, with results stratified by stage

- Timing of measure initiation:
  - ✓ Decision item 1. Please rank order the following options for the initiation of survival measurement
    - From time of diagnosis: [Enter rank 1, 2, 3]
    - From initiation of treatment: [Enter rank 1, 2, 3]
    - From completion of treatment: [Enter rank 1, 2, 3]
      - Please define 'treatment'. E.g., first treatment, regardless of type (surgery, systemic, radiation)? Other?: [Enter]

- Timing of measure calculation:
  - ✓ Decision item 2. What are the most meaningful timepoints for measuring melanoma survival (e.g., 1 year survival, 2 year survival, 5 year survival)? For those with localized disease? Regional? Metastatic?
    - [Enter]

- Denominator:
  - Adult patients with a melanoma diagnosis within measurement period
    - Note: 'Melanoma diagnosis' will be defined according to the data source
    - Note: patients included in the analysis will be those with sufficient elapsed time between diagnosis and measurement time-point

- Denominator exclusions: More than one cancer diagnosis within the measurement period
  - ✓ Decision item 3. Are there additional exclusions - any other cases where a patient should be removed from the analysis altogether?
    - [Enter]

- Numerator: Survival rate [within the defined time-points, above]
  - ✓ Decision item 4. What survival data are most meaningful? For example, hazard ratio with confidence intervals?
    - [Enter]
  - Note: data source that reliably captures death data is required

- Stratification: Survival rate will be stratified by stage categories
  - Note: the data source will dictate availability of staging information. If both clinical and pathological stage information is available, the combined AJCC stage group used by the NCDB can be considered.

- ✓ Decision item 5. Should stratification be by each stage (I, II, III, IV), or should stratification be by localized/regional/distant metastatic disease? (More stratification categories will lead to smaller Ns, which can be problematic, but stratified results should be as meaningful as possible). Select your preference:
  - Stratify by stage at diagnosis (I, II, III, IV): [Enter if your preference]
  - Stratify by localized disease vs regional disease vs distant metastatic disease at diagnosis: [Enter if your preference]
  - Other suggestion for stratification? [ENTER]
- ✓ Decision item 6. Should stratification separate patients who had non-metastatic disease at diagnosis, but then progressed to metastatic disease?
  - [Enter]

- Risk Adjustment:
  - ✓ Decision item 7. Please review the potential factors to test for risk adjustment. These should capture factors that impact survival, but are beyond the control of treating providers. Note: the data source for analysis may not provide all desired risk adjustment variables. At this point, identify risk adjustment variables which are desired. [Edit the list below – remove, add, modify risk adjustment variables]
    - Age
    - Sex
    - Race
    - Ethnicity
    - Education level
    - Insurance status
    - Income
    - Functional status (using standardized assessment)
    - Comorbidities (using standardized assessment)
    - BRAF mutation status
    - KIT mutation status
    - Surgical margin status
    - Elevated lactate dehydrogenase (LDH)
    - Hospital/facility factors [Enter specific factors if these should be tested for risk adjustment]
    - Geographic region of US

- Accountability/Attribution:
  - ✓ Decision item 8. Considering your responses to the questions above, which provider type(s) should be held accountable for overall survival for melanoma (that is, what is the unit of measurement)?
    - Hospitals [Enter yes or no]
    - Private practices [Enter yes or no]
    - Individual oncologists [Enter yes or no]

- ✓ Decision item 9. When attributing a patient to a provider to measure melanoma survival, which approach is preferred?
  - Each patient is attributed to only one provider (e.g., one hospital) [Enter yes or no]
  - Each patient can be attributed to multiple providers (e.g., multiple hospitals) if multiple providers were substantively involved in that patient's care [Enter yes or no]
- ✓ Decision item 10. Please rank order the following specific approaches to attribute patients to measure melanoma survival.
  - Attribute patients to the provider (e.g., hospital) that provided the majority of melanoma care (>50%) [Enter rank 1 2 3 4]
  - Attribute patients to the provider (e.g., hospital) that billed the majority of costs for melanoma care (>50%) [Enter rank 1 2 3 4]
  - Attribute patients to the provider (e.g., hospital) that provided a specific treatment (e.g., curative surgery, or the first systemic therapy) [Enter rank 1 2 3 4; enter comment re: which treatment]
  - Attribute patients to provider(s) that provided a plurality of melanoma care (e.g., >30%) [Enter rank 1 2 3 4]
  - Other approach: [Enter and rank]
- ✓ Decision item 11. Indicate the minimum number of patients which should be attributed to a provider in order for the survival rate to be calculated for that provider. For example, if a provider has only 4 patients attributed during the measurement period, should a survival rate be calculated? What minimum number will allow for meaningful analysis?
  - [Enter minimum number if the data will only be used for internal QI]
  - [Enter minimum number if the data will be publicly reported]

APPENDIX B. PROPOSED PRO-PM TESTING CRITERIA

For testing efficiency, it is recommended that NQF identify test sites that already have a history of reliable collection of the prioritized PRO data among the patient population for the measure. This will allow for use of historical data, augmented by some prospectively collected data (if needed) and clinical/demographic data. Site criteria for this testing approach are outlined below:

- Must use a PROM that includes at minimum the priority symptoms identified, and validated in the NSCLC population
- Must have ability to aggregate PROM data and clinical/demographic data for survey responders and non-responders
    - Clinical and demographic data required to calculate the population/denominator, denominator exclusions, numerator, and risk adjustment covariates
- Must have administered/offered PROM per defined schedule with following minimum requirements:
    - Administered at multiple defined points during chemotherapy (e.g., at least monthly; on every office visit)
- Must have administered the PROM for advanced/metastatic NSCLC patients and/or locally advanced NSCLC patients
- Must have a sufficient number of patients for whom data are complete (minimum N to be determined by statistician)

APPENDIX C. DATA ELEMENTS FOR MEASURE TESTING

LUNG	MELANOMA
Date of birth*	Date of birth
Date of diagnosis*	Date of diagnosis
Previous cancer diagnosis (yes/no and diagnosis)*	Previous cancer diagnosis (yes/no and diagnosis)
Concurrent cancer diagnosis (yes/no and diagnosis)*	Concurrent cancer diagnosis (yes/no and diagnosis)
Gender*	Gender
Ethnicity*	Ethnicity
Educational level*	Educational level
Insurance status*	Insurance status
Weight loss (previous 6 months)*	
Comorbidities*	Comorbidities
Patient-reported health status	Patient-reported health status
Smoking status*	Smoking status
Performance status*	Performance status
Pathologic stage (AJCC)*	Pathologic stage (AJCC)
Clinical stage (AJCC)*	Clinical stage (AJCC)
Cancer status (progression, relapse with dates)*	Cancer status (progression, relapse with dates)
Histology	Body region/primary tumor site
ALK translocation	
EGFR mutation	
ROS1 status	KIT status
BRAF status	BRAF status
PDL1 expression	
CNS involvement at dx (y/n)*	Brain mets at dx (y/n)
Elevated lactate dehydrogenase	Elevated lactate dehydrogenase
Time from diagnosis to treatment*	Time from diagnosis to treatment
Treatment intent	Treatment intent
Chemotherapy (type and dates)*	Chemotherapy (type and dates)
Targeted therapy (type and dates)*	Targeted therapy (type and dates)
Immunotherapy (type and dates)*	Immunotherapy (type and dates)
Surgery (type and dates)*	Surgery (type and dates)
Radiotherapy (type and dates)*	Radiotherapy (type and dates)
Global health status / Quality of life	Global health status / Quality of life
Date of death*	Date of death
Facility/practice characteristics*	Facility /practice characteristics
Pain*^	

Cough*^
Dyspnea*^
Appetite*^
Nausea/vomiting*^
Diarrhea*^
Constipation*^
Fatigue/sleep disturbance*^
Mental health PRO*^
Facility survey characteristics (e.g., response rates at each implementation; missing data at each implementation)*
*Items marked with * are for PRO-PM measures; with ^ are for PRO-PM only and not survival Note: for PRO-PM, data are required for eligible patients regardless of survey response status