URCC 13059

APPENDICES

Appendix A: Summary of Measures

Appendix B: Patient Measures

Appendix C: Clinical Research Associate Materials

Appendix D: Physician Measures

Appendix E: Study Related Forms

Appendix F: Approved Other Agents with Similar Prevalence of Toxicity to Chemotherapy

URCC 13059

APPENDIX A:
Summary of Measures

Collection Time-points are Screening/Baseline, 4-6 weeks, 10-14 weeks (3 months) and 20-26 weeks (6 months). Measures signified by [a] are only collected at screening/baseline and not at follow-up visits. Measures signified by [b] are collected only at follow-up visits.

We have piloted all measures. In total, geriatric assessment measures that are filled out by the patient require approximately 20 minutes of time. The additional measures captured at baseline require an additional 15 minutes of time. We have incorporated flexibility with timing in order to reduce patient burden. The follow-up questionnaires require about 30 minutes of time in total.

Patients and caregivers may complete geriatric assessment at clinic at time of consent or before next visit. They may choose to complete measures at home in between visits. We have found that 90% of patients complete measures at home if allowed to do so. The geriatric oncology clinic at the University of Rochester routinely captures these measures as part of clinical care.

The assessments performed by the Clinical Research Associate take 30 minutes of time in total (including physical performance and cognitive tests). Any person at the practice site can be trained by Research Base staff to do the assessments. The assessments do not need to be performed by the physician.

The physician assessments will be done either on paper or by email link to an on-line survey, whichever the physician prefers. The baseline assessments take no longer than 10 minutes and after each patient visit, the decision-making form (to assess factors that influenced decisions) is less than one-page long (2 minutes to complete).

1. Patient Surveys

1.1. *Demographics[a]:* Age, race and ethnicity, gender, highest level of education achieved, employment status, marital status, and presence of a living companion will be captured. We will also assess understanding of disease, self-rated health, and subjective age.

1.2. *Geriatric assessment:* Assessment tools comprising the comprehensive geriatric assessment are discussed below. The various assessment tools were selected based upon extensive data in the geriatric literature demonstrating predictive value as well as feasibility data in multiple studies of elderly patients with cancer. Other than the cognitive and physical performance measures, the assessments are self-administered. Patients who cannot complete the assessment on their own will receive assistance from the study personnel. The comprehensive assessment is performed prior to treatment and follow-up GA measures are collected at 4-6 weeks, 3 months, and 6 months.

1.2a. *Activities of daily living (ADL):*[1] ADLs are measures of self-care. ADL independence will be assessed using the Katz Index of Independence in Activities of Daily Living, commonly referred to as the Katz ADL. The Katz ADL is the most appropriate instrument to assess functional status as a measurement of the client's ability to perform activities of daily living independently. Clinicians typically use the tool to detect problems in performing activities of daily living and to plan care accordingly. The Index ranks adequacy of performance in the six functions of *bathing, dressing, toileting, transferring, continence, and feeding.* Clients are scored yes/no for independence in each of the six functions. A score of 6 indicates full function, 4 indicates moderate impairment, and 2 or less indicates severe functional impairment.

1.2b. *Instrumental Activities of Daily Living (IADL):*[1] Self-reported functional status will be assessed using the IADL subscale of the Multidimensional Functional Assessment Questionnaire: Older American Resources and Services (OARS). The IADL subscale

consists of seven questions rated on a three-point Likert scale. It measures the degree to which an activity can be performed independently.

1.2c. *Fall History:* A self-reported history of falls in the past six months will be recorded. A history of a recent fall has been demonstrated to be independently predictive of increased risk for chemotherapy toxicity in older cancer patients.[2]

1.2d. *OARS Physical Health:*[1] Self-reported questions that assess the degree of difficulty with physical tasks such as walking, climbing stairs, stooping, and reaching. This measure correlates with disability and comorbidity.

1.2e. *OARS Comorbidity*[a]*:*[1] Patients self-report their coexisting medical conditions and also rate the degree to which their illness causes impairment in daily activities. The OARS Physical Health Section has been shown to correlate significantly with health professional ratings of comorbidity as well.

1.2f. *OARS Medical Social Support survey and Social Activities:* [a 1] A 5-question survey asking patients to identify the number of support persons involved in their medical care as well as the degree to which they felt supported in a variety of situations. A follow-up question will be used to assess how much a patient's physical or emotional health interfered with *social activities*.

1.2g. *Generalized Anxiety Disorder 7 (GAD-7)*[a]*:*[3] The GAD-7 is a self-administered patient questionnaire used as a screening tool and severity measure for generalized anxiety disorder. The GAD-7 score is calculated by assigning scores of 0, 1, 2, and 3, to the response categories of "hardly ever," "several days," "more than half the days," and "nearly every day," respectively, and adding together the scores for the seven questions. Scores of 5, 10, and 15 are taken as the cut off points for mild, moderate, and severe anxiety, respectively. When used as a screening tool, further evaluation is recommended when the score is 10 or greater. Using the threshold score of 10, the GAD-7 has a sensitivity of 89% and a specificity of 82% for generalized anxiety disorder. It is moderately good at screening three other common anxiety disorders – panic disorder (sensitivity 74%, specificity 81%), social anxiety disorder (sensitivity 72%, specificity 80%), and post-traumatic stress disorder (sensitivity 66%, specificity 81%).

1.2h. *Geriatric Depression Scale (GDS):*[4] Patients will be screened with the Geriatric Depression Scale (GDS). The GDS contains questions that are intended to screen elderly patients for depression, while parsing out complaints related to advanced age.[5]

1.3. *Other Measures:*

1.3a. *PRO-CTCAE:* There is growing awareness that collecting symptom data directly from patients using patient-reported outcome (PRO) tools can improve the accuracy and efficiency of symptomatic AE data collection. This is based on findings from multiple studies demonstrating that physicians and nurses underestimate symptom onset, frequency, and severity in comparison with patient ratings. For example, in a study of men with prostate cancer enrolled in a Phase II clinical trial, physician reporting was neither sensitive nor specific in detecting common chemotherapy symptomatic adverse effects.[6]

In the field of pain management, it has long been recognized that only the patient can accurately report the onset, severity and duration of pain and its impact upon function. This principle extends to other symptoms, such as fatigue, erectile dysfunction, and xerostomia (dry mouth), which can be found in the CTCAE. The other advantages of a PRO complement to the CTCAE are discussed in an article by Trotti et al.[7]

The NCI's Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) system provides a platform to collect patient reports of symptoms they are experiencing while undergoing treatment, for the purpose of enhancing adverse event (AE) reporting http://outcomes.cancer.gov/tools/pro-ctcae.html). To date, 81 symptoms of the CTCAE (version 4) have been identified as amenable to patient reporting. These symptoms have been converted to patient terms (e.g., CTCAE term "myalgia" converted to "aching muscles").

For symptoms such as fatigue and pain, the PRO-CTCAE system asks patients for information about symptom frequency, severity, and interference with usual activities. For other symptoms (e.g., rash), questions focus on the presence or absence of the concern. These items have undergone extensive qualitative review among experts and patients.

1.3b. *Understanding of Disease* measures what the patient believes about their illness, and the influence on their quality of life and life expectancy.

1.3c. *Cancer Therapy Satisfaction Questionnaire (CTSQ):* We will also measure satisfaction with chemotherapy for those that were treated with chemotherapy.[8]

1.4. *Decision-Making Preferences*

For each physician-patient dyad, we will conduct assessments at study entry to assess factors that influence the decision to initiate chemotherapy (baseline), and we assess perceptions about the initial decision at 4-6 weeks, 3 months, and 6 months (follow-up).

1.4a. *Control Preferences Scale*[a 9] assesses whether patients and caregivers would want an active, passive, or shared decision-making process with their doctors. This tool has been validated for use in advanced cancer patients, older patients, and caregivers.[10, 11]

1.4b. *Decision Regret*[b 12-14] assesses distress or remorse regarding a prior health care decision. In the validation study, the scale showed good internal consistency (Cronbach's = 0.81 to 0.92). It correlated strongly with decision satisfaction (r = –0.40 to –0.60), decisional conflict (r =0.31 to 0.52), and overall rated quality of life (r = –0.25 to – 0.27). The tool has been utilized for assessing decisional regret for patients who underwent treatment for breast and prostate cancer.

1.4c. *SURE Test:*[a 15] The SURE test is a 4 item yes/no survey that assesses decisional conflict. Yes equals 1 point and no equals 0 points. A patient is experiencing decisional conflict if the score is less than 4.

2. CRA Packet (CRA fills out at visits)

2.1. *Tumor and Treatment Characteristics (patient):* The tumor stage, previous surgery or radiation, chemotherapy type, dosing, and schedule (intended and received will be captured by the CRA. The *Cancer Treatment History Form* will be used to collect the patient's previous treatments for his/her advanced cancer.

2.2. *Hematologic Toxicity Outcomes and Non-Hematologic Toxicity Outcomes (Clinician-rated CTCAE):* The NCI's Common Terminology Criteria for Adverse Events (CTCAE; http://ctep.cancer.gov/reporting/ctc.html) is a longstanding empirically developed "dictionary" or lexicon, designed for use in clinical trials to aid clinicians in detecting and documenting an array of adverse events (AEs) commonly encountered in oncology. An AE is any unfavorable sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or intervention that may or may *not* be considered related to the medical treatment or intervention under investigation. The AE may be either unexpected or expected.

An AE is a term that is a unique representation of a specific event used for medical documentation and scientific analyses of treatment efficacy and tolerability. Each AE is typically graded on a scale of 1 (mild) to 5 (death related to AE), though a grade 5 is not relevant for some AEs, such as hair loss or skin itching. The reporting requirements for AEs are generally protocol-specific and may be divided into two types. The first is the protocol-specific AEs to be addressed at designated evaluation intervals. The second is the pertinent positive clinical signs, symptoms, and laboratory results obtained as part of routine care of patients. The CTCAE is maintained by the NCI's Cancer Therapy Evaluation Program (CTEP). The CTCAE is currently in its fourth version.

2.3. *Supportive Care Medications Log*: The CRA will complete all supportive care medications that the patient is receiving on this log. Only changes and updates to supportive care need to be added during the study.

2.4. *Physician Rated KPS:* The CRA will obtain the physician's assessment of the impact of cancer and cancer treatment on the patient's overall function.

2.5. *Labs:* CRA will send results of routine laboratories collected including renal function and albumin.

2.6. *Polypharmacy* will be ascertained from the medical record after patients have been asked to review their medication list on file for any changes in the *Polypharmacy Log and Polypharmacy*

2.7. *Cancer Treatment Dosage Form* will be used to collect the patient's treatment regimen.

2.8. Geriatric Assessment

2.8.1. *Timed Up and Go*[a]*:*[16] The Timed Up & Go is a performance based test of functional status, measuring how many seconds it takes to stand up from a standard arm-chair, walk 3 meters (10 feet), turn, walk back to the chair, and sit down again. In community dwelling older adults, there was inter-rater and intra-rater reliability (intra-class correlation coefficient 0.99 for both).

2.8.2. *Mini-Cog:* A tool that is validated in the geriatric population to quickly assess cognitive impairment.[17, 18] The Mini-Cog takes approximately 3 minutes to administer. It has minimal language content, which reduces cultural and educational bias. It combines a 3-item recall component with a Clock Drawing Test.

2.8.3. *Blessed Orientation Memory Concentration (BOMC) Test*[a]*:* A six-question evaluation that screens for cognitive impairment. Studies have shown its validity as a screening instrument and the correlation of its results with those of more extensive mental status tests.[19]

2.8.4. *Nutritional Status and Mini Nutrition Assessment (MNA)*[a]*:* Screening for nutritional deficit will be performed with body mass index (BMI) evaluation and self-reported weight loss. Further nutritional evaluation will be performed with *the Mini-Nutritional Assessment (MNA)*[20], a well validated screening measure for nutritional deficiency which has shown to be prognostic of survival in older patients with cancer. Weight will be assessed at each time point. Height will be measured at baseline.

2.8.5. *Short Physical Performance Battery:*[21] Physical performance measures objectively evaluate mobility and fall risk. Falls are common in older cancer patients and predictive of adverse outcomes. *Short Physical Performance Battery (SPPB):* The SPPB is an objective physical assessment evaluating lower extremity physical

function. It is comprised of a four-meter walk, repeated chair stands and a balance test. Impairment on SPPB testing has been shown to be predictive of short-term mortality and nursing home admission in community-dwelling older adults.

3. Physician Assessment

3.1. *Physician Baseline Demographics and Treatment Preferences[a]:* Age, race and ethnicity, gender, and details on medical practice will be captured. We will also capture patient volume, and specify years of training after fellowship. The goal of shared decision-making is to make decisions in a manner consistent with the patient's wishes. The patient drives the process. Determining where on the shared decision-making continuum the patient feels most comfortable requires clear communication and dedicated time from the physician. Several studies have utilized the proposed measure for assessing the relationship of physician decision-making styles on clinical outcomes.[11, 22, 23]

3.2. *Situational Vignettes[a]:* Physicians will be presented with one of eight clinical scenario of an elderly cancer patient with a variety of geriatric-related impairments (i.e. physical frailty, cognitive impairment). A series of questions will follow each vignette inquiring about the likelihood of the physician to offer chemotherapy in the scenario and details regarding the regimen that would be considered (i.e. chemotherapy type, dosing, etc.). Three situational vignettes will be developed and with three factors (age, functional impairment, and cognitive impairment) varying in each vignette. For example, with one vignette, the patient with cancer is fit (young, without any impairment), in another, the patient is older, but without impairment, and in the third, the patient is younger with impairment. We will be able to compare decision-making for treatment, based on underlying factors. The survey will not be repeated with each subsequent patient.

3.3. *Physician Follow-up Survey[b]:* Physicians will complete a brief survey on REDCap, which will ask them about confidence in geriatrics and their opinion on the usefulness of the Geriatric Assessment (for intervention arm).

3.4. *Treatment Decision Making Form:* Physicians will complete a short (<10 question) survey follow-up requesting information on the treatment plan for the patient and factors that influenced how the decision was made. This follow-up survey is adapted from work by Dr. Dale and Dr. Mohile evaluating how decisions are made for starting hormonal treatment for prostate cancer.[24] Physicians will be asked to identify factors that influenced their decision in developing a treatment plan for each specific patient (i.e. age, stage of disease, performance status, geriatric measures). Physicians will rank each factor to determine which are most influential in their decision making process. Physicians will also be asked if results of geriatric assessment influenced their decision-making. If physicians have multiple patients enrolled on study, this survey will be completed for each individual patient.

3.5. *Decision Regret Follow-up[b]:* The Decisional Regret Scale assesses remorse regarding a prior health care decision. We have adapted the tool to evaluate the physician's perspective regarding regret for the prior decision of chemotherapy initiation.

3.6. *Understanding of Disease-Physician[a]:* Measures what the physician believes about the patient's future illness trajectory.

TABLES OF DATA TO BE KEPT

Patient Measures	**Screening Visit 00**	**Baseline Visit 01**	**4-6 Weeks Visit 02**	**3 Months Visit 03**	**6 Months Visit 04**
Demographics	Pt				
Activities of Daily Living (ADL)	Pt		Pt	Pt	Pt
IADL	Pt		Pt	Pt	Pt
Fall History	Pt		Pt (f/u)	Pt (f/u)	Pt (f/u)
OARS Physical Health	Pt		Pt	Pt	Pt
OARS Comorbidity	Pt				
OARS Medical Social Support	Pt				
Social Activities	Pt		Pt	Pt	Pt
GAD-7	Pt				
GDS	Pt		Pt	Pt	Pt
PRO-CTCAE		Pt	Pt	Pt	Pt
Control Preferences Scale		Pt			
Understanding of Disease		Pt	Pt		
Decision Regret			Pt	Pt	Pt
SURE Test		Pt			
CTSQ			Pt	Pt	Pt
Survey Completion	Pt		Pt	Pt	Pt

CRA and Physician Measures	Screening Visit 00	Baseline Visit 01	4-6 Weeks Visit 02	3 Months Visit 03	6 Months Visit 04
Screening Coversheet page 2[a]	CRA				
Baseline Coversheet[i]		CRA			
Tumor and Treatment Characteristics	CRA				
Cancer Treatment History		CRA			
Cancer Treatment Dosage Form[d]			CRA	CRA	CRA
Hematologic /Non- Hematologic Toxicity Outcomes[b]			CRA	CRA	
Supportive Care Medication Log[b]			CRA	CRA	CRA
Physician rated KPS	CRA		CRA	CRA	CRA
Labs	CRA				
Polypharmacy Log[c]	CRA		CRA	CRA	CRA
Polypharmacy High Risk Drug Review	CRA				
BOMC	CRA				
Mini-COG	CRA		CRA	CRA	CRA
Nutritional Status and MNA	CRA				
Timed "Up and Go"	CRA				
Short Physical Performance Battery	CRA		CRA	CRA	CRA
Geriatric Assessment Scoring Guide to Detect Impairments	CRA				
Cancer Treatment Status Form [e]		CRA	CRA (f/u)	CRA (f/u)	CRA (f/u)
Physician REDCap Baseline Survey	Phys				
Situational Vignettes[f]	Phys				
Physician Follow-Up Survey[g]					Phys
Treatment Decision Making Form		Phys			
Decision Regret Follow-up			Phys	Phys	Phys
Understanding of Disease -Physician		Phys			
Study Related Forms[h]					
Screening Log					
Patient Eligibility Checklist					
Patient Status/Withdrawal Form					
Physician Withdrawal Form					
Patient Survival Follow-up Form					
URCC CCOP Research Base AE Report					

Note: The measures/forms are not listed in the order of administration. Screening and baseline can be combined. [a]The Screening Coversheet page 2 collects patient information that will be used tohelp establish survival status. [b]The Hematologic/Non-Hematologic Toxicity Outcomes form and Supportive Care Medication log should be submitted to the Research Base after each cycle. The 6 month follow-up form is only completed for those participants who have remained on the same drug regimen throught out the study (even if the dosage has changed).[c]A copy of the most recent version of the polypharmacy log should be sent to the Research Base after each visit. After the 6 month follow-up visit, the completed polypharmacy log should be sent to the Research Base. [d]A copy of the Cancer Treatment Dosage Form should be sent to the research Base after each visit. After the 6 month follow-up visit, the completed Cancer Treatment Dosage Form should be sent to the Research Base. The 6 month follow-up form is only completed for those participants who have remained on the same drug regimen throught out the study (even if the dosage has changed). [e]The Cancer Treatment Status form will be completed when either a patient or physician decides stop cancer treatment. [f] The situational vignettes are collected as part of the Physician Baseline REDCap survey. [g]The final physician follow-up survey will be administered at the end of the study period or prior to a Physician withdrawing, for example, if they were to move or join another practice. [h]These forms will be used for study documentation purposes. [i]The questions on this forms will be used to determine who conducted the baseline visit.

Abbreviations: Pt (Patient); CRA (Clinical Research Associate); Phys (Physician); IADL (Instrumental Activities of Daily Living); GAD (Generalized Anxiety Disorder); General Depression Scale (GDS); KPS (Karnofsky Performance Status); PRO-CTCAE (Patient Reported Outcome – Common Terminology Criteria for Adverse Events); SURE (Sure of Myself, Understand information, Risk-benefit ratio; Encouragement); CTSQ (Cancer Therapy Satisfaction Questionnaire); SPPB (Short Physical Performance Battery)

Measures References

1. Hurria A, Gupta S, Zauderer M, et al. Developing a cancer-specific geriatric assessment: a feasibility study. *Cancer* 2005; **104**(9): 1998-2005.
2. Hurria A, Togawa K, Mohile SG, et al. Predicting chemotherapy toxicity in older adults with cancer: a prospective multicenter study. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2011; **29**(25): 3457-65.
3. Spitzer RL, Kroenke K, Williams JB, Lowe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Archives of internal medicine* 2006; **166**(10): 1092-7.
4. Parmelee PA, Katz IR. Geriatric depression scale. *Journal of the American Geriatrics Society* 1990; **38**(12): 1379.
5. Adams KB, Matto HC, Sanders S. Confirmatory factor analysis of the geriatric depression scale. *The Gerontologist* 2004; **44**(6): 818-26.
6. Fromme EK, Eilers KM, Mori M, Hsieh YC, Beer TM. How accurate is clinician reporting of chemotherapy adverse effects? A comparison with patient-reported symptoms from the Quality-of-Life Questionnaire C30. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2004; **22**(17): 3485-90.
7. Trotti A, Colevas AD, Setser A, Basch E. Patient-reported outcomes and the evolution of adverse event reporting in oncology. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2007; **25**(32): 5121-7.
8. Abetz L, Coombs JH, Keininger DL, et al. Development of the cancer therapy satisfaction questionnaire: item generation and content validity testing. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research* 2005; **8 Suppl 1**: S41-53.
9. Degner LF, Sloan JA, Venkatesh P. The Control Preferences Scale. *The Canadian journal of nursing research = Revue canadienne de recherche en sciences infirmieres* 1997; **29**(3): 21-43.
10. Singh JA, Sloan JA, Atherton PJ, et al. Preferred roles in treatment decision making among patients with cancer: a pooled analysis of studies using the Control Preferences Scale. *The American journal of managed care* 2010; **16**(9): 688-96.
11. Elkin EB, Kim SH, Casper ES, Kissane DW, Schrag D. Desire for information and involvement in treatment decisions: elderly cancer patients' preferences and their physicians' perceptions. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2007; **25**(33): 5275-80.
12. Davison BJ, Goldenberg SL. Decisional regret and quality of life after participating in medical decision-making for early-stage prostate cancer. *BJU international* 2003; **91**(1): 14-7.
13. Stryker JE, Wray RJ, Emmons KM, Winer E, Demetri G. Understanding the decisions of cancer clinical trial participants to enter research studies: factors associated with informed consent, patient satisfaction, and decisional regret. *Patient education and counseling* 2006; **63**(1-2): 104-9.
14. Brehaut JC, O'Connor AM, Wood TJ, et al. Validation of a decision regret scale. *Medical decision making : an international journal of the Society for Medical Decision Making* 2003; **23**(4): 281-92.
15. Legare F, Kearing S, Clay K, et al. Are you SURE?: Assessing patient decisional conflict with a 4-item screening test. *Canadian family physician Medecin de famille canadien* 2010; **56**(8): e308-14.
16. Podsiadlo D, Richardson S. The timed "Up & Go": a test of basic functional mobility for frail elderly persons. *Journal of the American Geriatrics Society* 1991; **39**(2): 142-8.
17. Borson S, Scanlan JM, Chen P, Ganguli M. The Mini-Cog as a screen for dementia: validation in a population-based sample. *J Am Geriatr Soc* 2003; **51**(10): 1451-4.
18. Costa D, Severo M, Fraga S, Barros H. Mini-Cog and Mini-Mental State Examination: agreement in a cross-sectional study with an elderly sample. *Dementia and geriatric cognitive disorders* 2012; **33**(2-3): 118-24.
19. Katzman R, Brown T, Fuld P, Peck A, Schechter R, Schimmel H. Validation of a short Orientation-Memory-Concentration Test of cognitive impairment. *The American journal of psychiatry* 1983; **140**(6): 734-9.
20. Zulian GB, Gold G, Herrmann F, Michel JP. Mini Nutritional Assessment and cancer. *Nestle Nutrition workshop series Clinical & performance programme* 1999; **1**: 93-8, 9-100.

21. Guralnik JM, Ferrucci L, Simonsick EM, Salive ME, Wallace RB. Lower-extremity function in persons over the age of 70 years as a predictor of subsequent disability. *The New England journal of medicine* 1995; **332**(9): 556-61.
22. Arora NK, Weaver KE, Clayman ML, Oakley-Girvan I, Potosky AL. Physicians' decision-making style and psychosocial outcomes among cancer survivors. *Patient education and counseling* 2009; **77**(3): 404-12.
23. Epstein RM, Street RL, Jr. Shared mind: communication, decision making, and autonomy in serious illness. *Annals of family medicine* 2011; **9**(5): 454-61.
24. Dale W, Hemmerich J, Bylow K, Mohile S, Mullaney M, Stadler WM. Patient anxiety about prostate cancer independently predicts early initiation of androgen deprivation therapy for biochemical cancer recurrence in older men: a prospective cohort study. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2009; **27**(10): 1557-63.

URCC 13059

APPENDIX B:
Patient Measures

1				

Patient ID

S				

Screening ID

Form	Version
URCC 13059 - GAP 70+ Demographics	Amd2

Patient Initials

● Screening

Instructions: Please answer the following questions about your background.

1. What is the highest grade you finished in school?

- ☐ 1-8 Grades
- ☐ 9-11 Grades
- ☐ High School Graduate
- ☐ Some College
- ☐ Junior College Degree
- ☐ College Degree (B.A./B.S.)
- ☐ Some Post-College
- ☐ Advanced Degree

2. What is your Marital Status?

- ☐ Single, Never Married
- ☐ Separated
- ☐ Widowed
- ☐ Married
- ☐ Domestic Partnership
- ☐ Divorced

3. With whom do you live? *(Mark an "X" for all that apply)*

- ☐ Spouse/Partner
- ☐ Children aged 19 or older
- ☐ Parent(s)
- ☐ In-laws
- ☐ Live Alone
- ☐ Other relative, specify: _____
- ☐ Children aged 18 or younger
- ☐ Other non-relative, specify: _____

4. How would you rate your health compared to others your age?

☐ Excellent ☐ Very Good ☐ Good ☐ Fair ☐ Poor

5. What is your current employment status? *(Mark an "X" for all that apply)*

- ☐ Employed ≥ 32 hours per week
- ☐ Employed < 32 hours per week
- ☐ Home Maker
- ☐ Full-Time Student
- ☐ Part-Time Student
- ☐ On Medical Leave
- ☐ Disabled
- ☐ Unemployed
- ☐ Retired
- ☐ Volunteer ≥ 20 Hours Per Week
- ☐ Volunteer < 20 Hours Per Week
- ☐ Other, Specify: ____

6. Are you driving?

☐ No ☐ Yes

7. How old are you? ☐☐☐ **years old.**

8. How old do you feel? ☐☐☐ **years old.**

9. What is your gender?

☐ Male ☐ Female

10. What is your ethnicity?

☐ Hispanic or Latino ☐ Non-Hispanic ☐ Unknown

11. What is your race? *(Mark an "X" for all that apply)*

- ☐ White
- ☐ Black or African American
- ☐ American Indian or Alaskan Native
- ☐ Asian
- ☐ Native Hawaiian or Other Pacific Islander

12. What kind of insurance do you have? *(Mark an "X" for all that apply)*

- ☐ Medicare
- ☐ Medicaid
- ☐ Private Insurance (such as Excellus, Aetna, etc.)
- ☐ Health Savings Account (HSA)
- ☐ Do Not Know/Not Sure
- ☐ No Insurance
- ☐ Other: ____

13. Think about your annual household income from all sources. In which of the following ranges does this income fall?

- ☐ Less than $20,000
- ☐ $20,000 to $50,000
- ☐ $50,001 to $100,000
- ☐ Over $100,000
- ☐ Decline to Answer

14. Please choose the description that best describes your living situation.

- ☐ Independent Living (More Than 1 Story)
- ☐ Assisted Living
- ☐ Independent Living (1 Story)
- ☐ Nursing Home/Skilled Nursing Living
- ☐ Independent Living in a Senior Living Facility

15. What services are available to you where you live? *(Mark an "X" for all that apply)*

- ☐ Social Work
- ☐ Physical Therapy/Occupational Therapy
- ☐ Oxygen Equipment
- ☐ Nutrition Support
- ☐ Medication Assistance
- ☐ Toileting Schedule
- ☐ Nightly Checks
- ☐ Transportation
- ☐ None

1 | | | | |

Patient ID

S | | | | |

Screening ID

Form	Version
URCC 13059 - GAP 70+ Activities of Daily Living (ADL)	Amd2

Patient Initials

● Screening

Instructions: Please mark an "**X**" in the check box that best corresponds to your answer for each question.

For columns B and/or C, if your answer is 'No', go to the next question.

	A Do you have **any difficulty** with the activity below?			**B** Are you **unable** to do this activity **on your own**?			**C** Are you **unable** to do this activity **on your own because** of a **health** or **physical problem**?	
Activity	**No**	**Yes**		**No**	**Yes**		**No**	**Yes**
1. Bathing or showering?	☐ *If **No** go to Ques. 2*	☐	If Yes →	☐	☐	If Yes →	☐	☐
2. Dressing?	☐ *If **No** go to Ques. 3*	☐	If Yes →	☐	☐	If Yes →	☐	☐
3. Eating?	☐ *If **No** go to Ques. 4*	☐	If Yes →	☐	☐	If Yes →	☐	☐
4. Getting in or out of bed or chairs?	☐ *If **No** go to Ques. 5*	☐	If Yes →	☐	☐	If Yes →	☐	☐
5. Walking?	☐ *If **No** go to Ques. 6*	☐	If Yes →	☐	☐	If Yes →	☐	☐
6. Using the toilet?	☐	☐	If Yes →	☐	☐	If Yes →	☐	☐

1					Patient ID

Form	Version
URCC 13059 - GAP 70+ Activities of Daily Living (ADL)	Amd2

			Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Instructions: Please mark an "**X**" in the check box that best corresponds to your answer for each question.

For columns B and/or C, if your answer is 'No', go to the next question.

	A Do you have **any difficulty** with the activity below?			**B** Are you **unable** to do this activity **on your own**?			**C** Are you **unable** to do this activity **on your own because** of a **health** or **physical problem**?	
Activity	**No**	**Yes**		**No**	**Yes**		**No**	**Yes**
1. Bathing or showering?	☐	☐ *If **No** go to Ques. 2*	If Yes →	☐	☐	If Yes →	☐	☐
2. Dressing?	☐	☐ *If **No** go to Ques. 3*	If Yes →	☐	☐	If Yes →	☐	☐
3. Eating?	☐	☐ *If **No** go to Ques. 4*	If Yes →	☐	☐	If Yes →	☐	☐
4. Getting in or out of bed or chairs?	☐	☐ *If **No** go to Ques. 5*	If Yes →	☐	☐	If Yes →	☐	☐
5. Walking?	☐	☐ *If **No** go to Ques. 6*	If Yes →	☐	☐	If Yes →	☐	☐
6. Using the toilet?	☐	☐	If Yes →	☐	☐	If Yes →	☐	☐

1				

Patient ID

S				

Screening ID

Form	Version
URCC 13059 - GAP 70+ Instrumental Activities of Daily Living (IADL)	Amd2

Patient Initials

● Screening

Instructions: The following questions are asking whether you are able to do an activity, even if you typically do not do that specific activity. Please mark an "**X**" for one answer to each question.

1. Can you use the telephone?

- ☐ Without help, including looking up and dialing
- ☐ With some help (can answer phone in an emergency, but need a special phone or help in getting the number or dialing)
- ☐ Completely unable to use the telephone

2. Can you get to places out of walking distance?

- ☐ Without help (drive your own car, or travel alone on buses or taxis)
- ☐ With some help (need someone to help you or go with you when traveling)
- ☐ Completely unable to travel unless arrangements are made for a specialized vehicle

3. Can you go shopping for groceries or clothes?

- ☐ Without help (taking care of most shopping needs yourself, assuming you have transportation)
- ☐ With some help (need someone to go with you on most shopping trips)
- ☐ Completely unable to do any shopping

4. Can you prepare your own meals?

- ☐ Without help (plan and cook most full meals yourself)
- ☐ With some help (can prepare some things but unable to cook full meals yourself)
- ☐ Completely unable to prepare any meals

5. Can you do your housework?

- ☐ Without help (for example, clean floors)
- ☐ With some help (can do light housework but need help with heavy work)
- ☐ Completely unable to do any housework

6. Can you take your own medicine?

- ☐ Without help (in the right doses at the right time)
- ☐ With some help (able to take medicine if someone prepares it for you and/or reminds you to take it)
- ☐ Completely unable to take your medicines by yourself

7. Can you handle your own money?

- ☐ Without help (for example write checks or pay bills)
- ☐ With some help (manage day-to-day spending but need help with managing your checkbook and paying your bills)
- ☐ Completely unable to handle money

1				

Patient ID

Form	Version
URCC 13059 - GAP 70+ Instrumental Activities of Daily Living (IADL)	Amd2

Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Instructions: The following questions are asking whether you are able to do an activity, even if you typically do not do that specific activity. Please mark an "**X**" for one answer to each question.

1. Can you use the telephone?

☐ Without help, including looking up and dialing

☐ With some help (can answer phone in an emergency, but need a special phone or help in getting the number or dialing)

☐ Completely unable to use the telephone

2. Can you get to places out of walking distance?

☐ Without help (drive your own car, or travel alone on buses or taxis)

☐ With some help (need someone to help you or go with you when traveling)

☐ Completely unable to travel unless arrangements are made for a specialized vehicle

3. Can you go shopping for groceries or clothes?

☐ Without help (taking care of most shopping needs yourself, assuming you have transportation)

☐ With some help (need someone to go with you on most shopping trips)

☐ Completely unable to do any shopping

4. Can you prepare your own meals?

☐ Without help (plan and cook most full meals yourself)

☐ With some help (can prepare some things but unable to cook full meals yourself)

☐ Completely unable to prepare any meals

5. Can you do your housework?

- ☐ Without help (for example, clean floors)
- ☐ With some help (can do light housework but need help with heavy work)
- ☐ Completely unable to do any housework

6. Can you take your own medicine?

- ☐ Without help (in the right doses at the right time)
- ☐ With some help (able to take medicine if someone prepares it for you and/or reminds you to take it)
- ☐ Completely unable to take your medicines by yourself

7. Can you handle your own money?

- ☐ Without help (for example write checks or pay bills)
- ☐ With some help (manage day-to-day spending but need help with managing your checkbook and paying your bills)
- ☐ Completely unable to handle money

1 Patient ID

S Screening ID

Form	Version
URCC 13059 - GAP 70+ Fall History	Amd2

Patient Initials

● Screening

Instructions: Please mark an "**X**" in the check box that best corresponds to your answer for each question.

1. In the past 6 months, have you fallen down?

☐ No ☐ Yes

If you answered NO to question 1, please skip to question 2.

1a. About how long ago was your most recent fall? ☐ months ago / ☐☐ days ago

1b. In the past year, how many times have you fallen down?

☐☐☐

☐ I Don't Know

1c. Did you hurt yourself badly enough to get medical help from any of those falls?

☐ No ☐ Yes

2. In the past 12 months, how worried or afraid are you that you might fall?

☐ Not At All Afraid ☐ Slightly Afraid ☐ Somewhat Afraid ☐ Very Afraid

3. Do you ever limit your activities for example, what you do or where you go, because you are afraid of falling?

☐ No ☐ Yes

1	Form	Version	
Patient ID	**URCC 13059 - GAP 70+** Fall History Follow-up	Amd2	Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Instructions: Please mark an "**X**" in the check box that best corresponds to your answer for each question.

1. Have you had a new fall since the last assessment?

☐ No ☐ Yes

If NO to question 1, skip to question 2.

1a. About how long ago was your most recent fall? ☐ months ago / ☐☐ days ago

1b. How many times have you fallen down?

☐☐☐

☐ I Don't Know

1c. Did you hurt yourself badly enough to get medical help from any of those falls?

☐ No ☐ Yes

2. Since the last assessment, how worried or afraid are you that you might fall?

☐ Not At All Afraid ☐ Slightly Afraid ☐ Somewhat Afraid ☐ Very Afraid

3. Since the last assessment, do you ever limit your activities, for example, what you do or where you go, because you are afraid of falling?

☐ No ☐ Yes

1				

Patient ID

S				

Screening ID

Form	Version
URCC 13059 - GAP 70 + OARS Physical Health	Amd2

Patient Initials

● Screening

Instructions: The following items are activities you might do during a typical day. Please place an **"X"** in the check box that best corresponds to your answer for each question. Does your health limit you *"a lot," "a little,"* or *"not at all"*?

Activities	**A Lot**	**A Little**	**Not at All**
1. Vigorous activities, such as running, lifting heavy objects, participating in strenuous activities.	☐	☐	☐
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	☐	☐	☐
3. Lifting or carrying groceries.	☐	☐	☐
4. Climbing several flights of stairs.	☐	☐	☐
5. Climbing one flight of stairs.	☐	☐	☐
6. Bending, kneeling, or stooping.	☐	☐	☐
7. Walking more than a mile.	☐	☐	☐
8. Walking several blocks.	☐	☐	☐
9. Walking one block.	☐	☐	☐
10. Bathing or dressing yourself.	☐	☐	☐

1				

Patient ID

Form	Version
URCC 13059 - GAP 70 + OARS Physical Health	Amd2

Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Instructions: The following items are activities you might do during a typical day. Please place an **"X"** in the check box that best corresponds to your answer for each question. Does your health limit you *"a lot," "a little,"* or *"not at all"*?

Activities	**A Lot**	**A Little**	**Not at All**
1. Vigorous activities, such as running, lifting heavy objects, participating in strenuous activities.	☐	☐	☐
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	☐	☐	☐
3. Lifting or carrying groceries.	☐	☐	☐
4. Climbing several flights of stairs.	☐	☐	☐
5. Climbing one flight of stairs.	☐	☐	☐
6. Bending, kneeling, or stooping.	☐	☐	☐
7. Walking more than a mile.	☐	☐	☐
8. Walking several blocks.	☐	☐	☐
9. Walking one block.	☐	☐	☐
10. Bathing or dressing yourself.	☐	☐	☐

1 | | | | |
Patient ID

S | | | | |
Screening ID

Form	Version
URCC 13059 - GAP 70+ OARS Comorbidity	Amd2

Patient Initials

● Screening

Instructions: We would like to ask you a few questions about any health problems you might have. Do you have any of the following illnesses at the present time?

Please mark the box with an **"X"** for the appropriate response (yes or no).

If you choose **Yes** please tell us how much the illness interferes with your activities.

				IF YOU HAVE THIS ILLNESS: How much does it interfere with your activities?		
Illness	**No**	**Yes**		**Not At All**	**Somewhat**	**A Great Deal**
1. Other cancer or leukemia	☐	☐	**If Yes →**	☐	☐	☐
2. Arthritis or rheumatism	☐	☐	**If Yes →**	☐	☐	☐
3. Glaucoma	☐	☐	**If Yes →**	☐	☐	☐
4. Emphysema or chronic bronchitis	☐	☐	**If Yes →**	☐	☐	☐
5. High blood pressure	☐	☐	**If Yes →**	☐	☐	☐
6. Heart disease	☐	☐	**If Yes →**	☐	☐	☐
7. Circulation trouble in arms or legs	☐	☐	**If Yes →**	☐	☐	☐
8. Diabetes	☐	☐	**If Yes →**	☐	☐	☐
9. Stomach or intestinal disorders	☐	☐	**If Yes →**	☐	☐	☐
10. Osteoporosis	☐	☐	**If Yes →**	☐	☐	☐
11. Chronic liver or kidney disease	☐	☐	**If Yes →**	☐	☐	☐
12. Stroke	☐	☐	**If Yes →**	☐	☐	☐
13. Depression	☐	☐	**If Yes →**	☐	☐	☐

For CRA Use Only:
Number of Conditions (Sum) = | |

14. How is your eyesight (with glasses or contacts)?

☐ Totally Blind ☐ Poor ☐ Fair ☐ Good ☐ Excellent

14a. (If Fair to Totally Blind): How much does it interfere with your activities?

☐ Not At All ☐ Somewhat ☐ A Great Deal

15. How is your hearing (with a hearing aid, if needed)?

☐ Deaf ☐ Poor ☐ Fair ☐ Good ☐ Excellent

15a. (If Fair to Deaf): How much does it interfere with your activities?

☐ Not At All ☐ Somewhat ☐ A Great Deal

1 Patient ID

S Screening ID

Form	Version
URCC 13059 - GAP 70 + OARS Medical Social Support	Amd2

Patient Initials

● Screening

Instructions: Please answer the following questions.

1. About how many close friends and close relatives do you have now (people you feel at ease with and can talk to about what is on your mind)? ☐☐☐

Please mark an "X" in the box that best describes your life.

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
2. Is there someone to help, if you were confined to bed?	☐	☐	☐	☐	☐
3. Is there someone to take you to the doctor if needed?	☐	☐	☐	☐	☐
4. Is there someone to prepare your meals if you were unable to do it yourself?	☐	☐	☐	☐	☐
5. Is there someone to help you with daily chores if you were sick?	☐	☐	☐	☐	☐

1				

Patient ID

S				

Screening ID

Form	Version
URCC 13059 - GAP 70+ Social Activities	Amd2

Patient Initials

● Screening

Instructions: Please mark an **"X"** in the check box that best corresponds to your answer to the question.

1. During the <u>past 4 weeks</u>, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

1				

Patient ID

Form	Version
URCC 13059 - GAP 70+ Social Activities Follow-up	Amd2

Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Instructions: Please mark an "**X**" in the check box that best corresponds to your answer to the question.

1. During the <u>past 4 weeks</u>, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

1 | | | | |

Patient ID

S | | | | |

Screening ID

Form	Version
URCC 13059 - GAP 70+ GAD-7	Amd2

	Patient Initials

● Screening

Instructions: The question below asks you about <u>your</u> mood over the last <u>2 weeks</u>.
Please answer the following question:

How often have <u>you</u> been bothered by the following problems?	**Hardly Ever (0)**	**Several Days (1)**	**More Than Half The Days (2)**	**Nearly Every Day (3)**
1. Feeling nervous, anxious or on edge	☐	☐	☐	☐
2. Not being able to stop or control worrying	☐	☐	☐	☐
3. Worrying too much about different things	☐	☐	☐	☐
4. Trouble relaxing	☐	☐	☐	☐
5. Being so restless that it is hard to sit still	☐	☐	☐	☐
6. Becoming easily annoyed or irritable	☐	☐	☐	☐
7. Feeling afraid as if something awful might happen	☐	☐	☐	☐

(For CRA Use Only: Total ☐☐ **=** **0** **+** ____ **+** ____ **+** ____ **)**

1				

Patient ID

S				

Screening ID

Form	Version
URCC 13059 - GAP 70+ GDS	Amd2

Patient Initials

● Screening

Instructions: Please mark an **"X"** in the check box that best corresponds to your answer for each question.

	Yes	No
1. Are you basically satisfied with your life?	☐	☐
2. Have you dropped many of your activities and interests?	☐	☐
3. Do you feel that your life is empty?	☐	☐
4. Do you often get bored?	☐	☐
5. Are you in good spirits most of the time?	☐	☐
6. Are you afraid that something bad is going to happen to you?	☐	☐
7. Do you feel happy most of the time?	☐	☐
8. Do you often feel helpless?	☐	☐
9. Do you prefer to stay home, rather than going out and doing new things?	☐	☐
10. Do you feel you have more problems with memory than most?	☐	☐
11. Do you think it is wonderful to be alive now?	☐	☐
12. Do you feel pretty worthless the way you are now?	☐	☐
13. Do you feel that your life is full of energy?	☐	☐
14. Do you feel your situation is hopeless?	☐	☐
15. Do you think that most people are better off than you are?	☐	☐

(For CRA Use Only: Total ☐☐ **=_____ + _____)**

1					Form	Version			
Patient ID					**URCC 13059 - GAP 70+** GDS	Amd2			Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Instructions: Please mark an **"X"** in the check box that best corresponds to your answer for each question.

	Yes	No
1. Are you basically satisfied with your life?	☐	☐
2. Have you dropped many of your activities and interests?	☐	☐
3. Do you feel that your life is empty?	☐	☐
4. Do you often get bored?	☐	☐
5. Are you in good spirits most of the time?	☐	☐
6. Are you afraid that something bad is going to happen to you?	☐	☐
7. Do you feel happy most of the time?	☐	☐
8. Do you often feel helpless?	☐	☐
9. Do you prefer to stay home, rather than going out and doing new things?	☐	☐
10. Do you feel you have more problems with memory than most?	☐	☐
11. Do you think it is wonderful to be alive now?	☐	☐
12. Do you feel pretty worthless the way you are now?	☐	☐
13. Do you feel that your life is full of energy?	☐	☐
14. Do you feel your situation is hopeless?	☐	☐
15. Do you think that most people are better off than you are?	☐	☐

(For CRA Use Only: Total ☐☐ **=** _____ **+** _____ **)**

1					Form	Version		
Patient ID					**URCC 13059 - GAP 70+** PRO-CTCAE	Amd2		Patient Initials

○ Baseline ○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Instructions: As individuals go through treatment for their cancer they sometimes experience different symptoms and side effects. For each question, please mark an **"X"** in the one box that best describes your experiences over the **past 7 days.**

For the symptoms below, the first question asks about the **frequency** ("How often did you have this symptom?"). If you answer **"never,"** please skip to the next symptom. Otherwise answer the follow-up questions about the **severity** ("What was the severity at its worst?"), and/or **Interferes with daily activities** ("How much did the symptom interfere with your usual or daily activities?").

1. How often did you have **arm or leg swelling?** ☐ NEVER (If never, skip to question 2)

a. Frequency		☐ Rarely	☐ Occasionally	☐ Frequently	☐ Almost Constantly
b. Severity	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe
c. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

2. How often did you have **pain?** ☐ NEVER (If never, skip to question 3)

a. Frequency		☐ Rarely	☐ Occasionally	☐ Frequently	☐ Almost Constantly
b. Severity	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe
c. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

3. How often did you have **headaches?** ☐ NEVER (If never, skip to question 4)

a. Frequency		☐ Rarely	☐ Occasionally	☐ Frequently	☐ Almost Constantly
b. Severity	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe
c. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

4. How often did you have **nausea?** ☐ NEVER (If never, skip to question 5)

a. Frequency		☐ Rarely	☐ Occasionally	☐ Frequently	☐ Almost Constantly
b. Severity	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe

5. How often did you have **vomiting?** ☐ NEVER (If never, skip to question 6)

a. Frequency		☐ Rarely	☐ Occasionally	☐ Frequently	☐ Almost Constantly
b. Severity	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe

6. How often did you have **loose or watery stools (diarrhea)?**
☐ NEVER (If never, skip to question 7)

a. Frequency		☐ Rarely	☐ Occasionally	☐ Frequently	☐ Almost Constantly
b. Severity	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe

7. How often did you **lose control of your bowels?** ☐ NEVER (If never, skip to question 8)

a. Frequency		☐ Rarely	☐ Occasionally	☐ Frequently	☐ Almost Constantly
b. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

8. How often did you **lose control of urination?** ☐ NEVER (If never, skip to question 9)

a. Frequency		☐ Rarely	☐ Occasionally	☐ Frequently	☐ Almost Constantly
b. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

9. What was the severity of your **fatigue, tiredness, or lack of energy** at its worst?

☐ NONE (If none, skip to question 10)

a. Severity	☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe	
b. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

10. What was the severity of your **decreased appetite** at its worst?

☐ NONE (If none, skip to question 11)

a. Severity	☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe	
b. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

11. What was the severity of your **numbness or tingling in hands or feet** at its worst?

☐ NONE (If none, skip to question 12)

a. Severity	☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe	
b. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

12. What was the severity of your **blurry vision** at its worst?

☐ NONE (If none, skip to question 13)

a. Severity	☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe	
b. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

13. What was the severity of your **shortness of breath** at its worst?

☐ NONE (If none, skip to question 14)

a. Severity	☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe	
b. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

14. What was the severity of your **insomnia, including difficulty falling asleep, staying asleep, or waking up early** at its worst? ☐ NONE (If none, skip to question 15)

a. Severity		☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe
b. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

15. What was the severity of your **problems tasting food or drink** at its worst?
☐ NONE (If none, skip to question 16)

a. Severity		☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe
b. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

16. What was the severity of your **dizziness** at its worst? ☐ NONE (If none, skip to question 17)

a. Severity		☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe
b. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

17. What was the severity of your **mouth and throat sores** at its worst?
☐ NONE (If none, skip to question 18)

a. Severity		☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe
b. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

18. What was the severity of your **problems with concentration** at its worst?
☐ NONE (If none, skip to quesiton 19)

a. Severity		☐ Mild	☐ Moderate	☐ Severe	☐ Very Severe
b. Interferes with Daily Activities	☐ Not At All	☐ A Little Bit	☐ Somewhat	☐ Quite a Bit	☐ Very Much

19. What was the severity of your **problems with memory** at its worst?

☐ NONE (If none, skip to question 20)

a. Severity ☐ Mild ☐ Moderate ☐ Severe ☐ Very Severe

b. Interferes with Daily Activities ☐ Not At All ☐ A Little Bit ☐ Somewhat ☐ Quite a Bit ☐ Very Much

For the symptoms below, what was the **severity** at its worst?

	None	Mild	Moderate	Severe	Very Severe
20. Constipation	☐	☐	☐	☐	☐
21. Difficulty Swallowing	☐	☐	☐	☐	☐
22. Dry Mouth	☐	☐	☐	☐	☐
23. Hand-Foot Syndrome	☐	☐	☐	☐	☐
24. Ringing in your ears	☐	☐	☐	☐	☐
25. Skin cracking at the corners of your mouth	☐	☐	☐	☐	☐

26. Did you have any **hair loss? (In the last 7 days)**

☐ Not At All ☐ A Little Bit ☐ Somewhat ☐ Quite a Bit ☐ Very Much

27. Did you have a **rash? (In the last 7 days)**

☐ No ☐ Yes

28. Do you have any **other symptoms** you wish to report? *(If yes, please list them in the table below)*

☐ No ☐ Yes

For each symptom, what was the severity of this symptom at its WORST?

	Other Symptoms	None	Mild	Moderate	Severe	Very Severe
28a.		☐	☐	☐	☐	☐
28b.		☐	☐	☐	☐	☐
28c.		☐	☐	☐	☐	☐
28d.		☐	☐	☐	☐	☐
28e.		☐	☐	☐	☐	☐
28f.		☐	☐	☐	☐	☐

1					Form	Version			
Patient ID					**URCC 13059 - GAP 70+** Control Preferences Scale	Amd2			Patient Initials

● Baseline

INSTRUCTIONS
For **Question 1** **:** Circle the number that best represents your preference for information.
For **Questions 2-4** **:** Place an "**X**" in the checkbox next to the answer that best fits you.

1. Some patients prefer to have very few details about their illness while others prefer to have as many details as possible. On the scale of 1 to 5 shown below, please circle the number that best represents your preference for information.

1 2 3 4 5

I prefer as **few** details as possible ⟷ I prefer as **many** details as possible

2. Which of the following statements best describes how you feel?

- ☐ I want only information needed to care for myself properly.
- ☐ I want additional information only if it is good news.
- ☐ I want as much information as possible, good and bad.

3. Some patients prefer to leave decisions about treatment up to their doctor, while others prefer to participate in these decisions.

- ☐ The CANCER DOCTOR should make the decisions using all that's known about the treatments.
- ☐ The CANCER DOCTOR should make the decisions but strongly consider the patient's needs and priorities.
- ☐ The CANCER DOCTOR AND PATIENT should make the decisions together on an equal basis.
- ☐ The PATIENT should make the decisions, but strongly consider the doctor's opinion.
- ☐ The PATIENT should make the decisions using all they know or learn about the treatments.

4. Please mark an "X" next to the statement that best describes your caregiver's role in decisions about your treatment. (mark NA if you don't have a caregiver)

- ☐ The CANCER DOCTOR should make the decisions using all that's known about the treatments.
- ☐ The PATIENT should make treatment decisions with the doctor.
- ☐ The PATIENT AND CAREGIVER should make treatment decisions with the doctor.
- ☐ The CAREGIVER should make treatment decisions with the doctor.
- ☐ NA

1					Patient ID

Form	Version
URCC 13059 - GAP 70+ Understanding of Disease	Amd2

			Patient Initials

○ Baseline ○ 4-6 Weeks

Instructions: Please indicate how strongly you agree with the following statements. Mark an "**X**" in the box that corresponds to your level of agreement.

1. I would like to try treatments for my cancer if they could help me live longer, even if it is very likely they would...	**Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
a. have high level of side effects (such as nausea/vomiting).	☐	☐	☐	☐	☐
b. make me bedbound and unable to use the bathroom without assistance.	☐	☐	☐	☐	☐
c. make me require more assistance from family and friends with completing daily activities (such as shopping and managing money).	☐	☐	☐	☐	☐
d. make my memory worse.	☐	☐	☐	☐	☐
e. cause me to become confused often so that I am not aware of my surroundings.	☐	☐	☐	☐	☐
2. Maintaining my quality of life is more important to me than living longer.	☐	☐	☐	☐	☐

○ Baseline ○ 4-6 Weeks

Instructions: The following are questions about what you believe about your illness. There are no right or wrong answers. They ask about your quality of life and how long you think you might live. We understand that it might be difficult to answer some of these questions and we appreciate you making your best guess.

3. To what extent have you discussed your prognosis with your cancer doctor?

☐ Completely ☐ Mostly ☐ A Little ☐ Not At All

4. To the best of your knowledge, is your cancer curable?

☐ Yes ☐ No ☐ Uncertain

5. What do you believe are the chances that your cancer will go away and never come back with treatment?

☐ 100% ☐ More than 50% ☐ 50/50 ☐ Less than 50%

☐ 0% ☐ Uncertain

6. How much time do you expect cancer treatment (e.g. chemotherapy) to add to your life?

☐ None ☐ Less than 1 month ☐ 1 to 3 months ☐ 4 to 6 months

☐ 7 to 12 months ☐ More than 1 year ☐ Decline to answer

1				

Patient ID

Form	Version
URCC 13059 - GAP 70+ Decision Regret	Amd2

Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Instructions: Please show how strongly you agree or disagree with these statements by marking the box with an "**X**" that best fits your views about your decisions for your cancer care.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. I believe the right decisions have been made.	☐	☐	☐	☐	☐
2. I regret the choices that were made.	☐	☐	☐	☐	☐
3. I would make the same choices if I had to do it over again.	☐	☐	☐	☐	☐
4. The choices did me a lot of harm.	☐	☐	☐	☐	☐
5. The decisions were wise.	☐	☐	☐	☐	☐

1					Form	Version			
Patient ID					**URCC 13059 - GAP 70+** SURE Test	Amd2			Patient Initials

● Baseline

Instructions: The questions below ask you how you feel about **your decision to begin cancer treatment (e.g. chemotherapy).** After each question, please mark an **"X"** in the box below the **YES** or **NO**

	Yes	No
1. Do you feel SURE about the best choice for you?	☐	☐
2. Do you know the benefits and risks of each option?	☐	☐
3. Are you clear about which benefits and risks matter most to you?	☐	☐
4. Do you have enough support and advice to make a choice?	☐	☐

1					Form	Version		
Patient ID					**URCC 13059 - GAP 70+** Cancer Therapy Satisfaction Questionnaire (CTSQ)	Amd2		Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Instructions: The following page ask some questions about your cancer therapy (IV/pills). Within this questionnaire, "Cancer therapy (IV/pills)" refers to your current or most recent cancer therapy or cancer pills (including: hormonal therapy, IV therapy, and cancer pills). Please read each question and answer as honestly as you can without the help of anyone. There are no right or wrong answers; the answers should be based on your own personal experiences.

Satisfaction With Cancer Therapy (IV/pills)

Instructions: The following statements are about your satisfaction with your **most recent cancer therapy** (IV/pills). Please answer each question below by *checking the box* that best describes your level of satisfaction (check only one box per question).

1. Overall, how worthwhile was your cancer therapy (IV/pills)?

☐ Very Worthwhile ☐ Quite Worthwhile ☐ Moderately Worthwhile ☐ A Little Worthwhile ☐ Not At All Worthwhile

2. Overall, was taking cancer therapy (IV/pills) as difficult as you expected?

☐ Much more difficult than I thought it would be ☐ Somewhat more difficult than I thought it would be ☐ As difficult as I thought it would be ☐ Somewhat easier than I thought it would be ☐ Much easier than I thought it would be

3. Overall, how well did the **benefits** of cancer therapy (IV/pills) meet your expectations?

☐ Much better than my expectations ☐ Somewhat better than my expectations ☐ Met my expectations ☐ Somewhat worse than my expectations ☐ Much worse than my expectations

4. Overall, were the side **effects** of cancer therapy (IV/pills) as you expected?

☐ Much better than I expected ☐ Somewhat better than I expected ☐ Exactly as I expected ☐ Somewhat worse than I expected ☐ Much worse than I expected

5. How satisfied were you with the **form** of your cancer therapy (IV/pills)?

☐ Very Satisfied ☐ Satisfied ☐ Neutral ☐ Dissatisfied ☐ Very Dissatisfied

6. Overall, how satisfied were you with your most recent cancer therapy (IV/pills)?

☐ Very Satisfied ☐ Satisfied ☐ Neutral ☐ Dissatisfied ☐ Very Dissatisfied

7. Taking everything into consideration, if given the choice again, would you decide to take this cancer therapy treatment?

☐ Yes, definitely ☐ Probably yes ☐ I don't know ☐ Probably Not ☐ Definitely Not

1				

Patient ID

S				

Screening ID

Form	Version
URCC 13059 - GAP 70+ Survey Completion	Amd2

Patient Initials

● Screening

Instructions: Please place an "**X**" in the check box that best corresponds to your answer for each question.

1. Where did you complete these questionnaires? (Choose **one** response)

- ☐ At Home
- ☐ Doctor's Office
- ☐ At Home and Doctor's Office
- ☐ Other Location

2. Did someone help you complete these questionnaires?

- ☐ No → Skip Questions 3 and 4
- ☐ Yes

3. If **yes**, who? (Mark an **"X"** for all that apply)

- ☐ Caregiver
- ☐ Clinical Research Associate (CRA)
- ☐ Caregiver and CRA
- ☐ Other

4. How did that person(s) help you? (Mark an **"X"** for all that apply)

- ☐ Read the questions to me
- ☐ Wrote down the answers I gave
- ☐ Answered the questions for me
- ☐ Helped in some other way (Please Print)

1					Form	Version			
Patient ID					**URCC 13059 - GAP 70+** Survey Completion	Amd2			Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Instructions: Please place an "**X**" in the check box that best corresponds to your answer for each question.

1. Where did you complete these questionnaires? (Choose **one** response)

- ☐ At Home
- ☐ Doctor's Office
- ☐ At Home and Doctor's Office
- ☐ Other Location

2. Did someone help you complete these questionnaires?

- ☐ No → Skip Questions 3 and 4
- ☐ Yes

3. If **yes**, who? (Mark an **"X"** for all that apply)

- ☐ Caregiver
- ☐ Clinical Research Associate (CRA)
- ☐ Caregiver and CRA
- ☐ Other

4. How did that person(s) help you? (Mark an **"X"** for all that apply)

- ☐ Read the questions to me
- ☐ Wrote down the answers I gave
- ☐ Answered the questions for me
- ☐ Helped in some other way (Please Print)

URCC 13059

APPENDIX C:
Clinical Research Associate Materials

1 | | | | |

Patient ID

| | | |

Patient Initials

S | | | | |

Screening ID

13059 - GAP 70+ (Amd2) CRA Administered Assessments Screening

Survey Date: | | | / | | | / | | | | |

mm dd yyyy

| | | | |

Physician ID

Visit #: 0 0

1 | | | | |

Patient ID

Patient Initials

S | | | | |

Screening ID

This information will be kept confidential.

The information provided will be solely used to establish survival status.

LAST Name:

FIRST Name:

MIDDLE Name:

Date of Birth: | | / | | / | | | | |

Gender: ○ Male ○ Female

1 | | | | |

Patient ID

| | | |

Patient Initials

13059 - GAP 70+ (Amd2) CRA Administered Assessments Baseline

Survey Date: | | | / | | | / | | | | |

mm dd yyyy

Visit #: 0 1

1.A Did the **Oncology Physician** attend the baseline visit with the patient?

- ☐ Yes (Full visit)
- ☐ Yes (Partial Visit)
- ☐ No

1.B If **Yes (Partial Visit)** or **No** which member of the oncology team conducted the visit?

- ☐ NP
- ☐ PA
- ☐ Oncology Fellow
- ☐ Other Advanced Practice Practitioner(APP)

1 | | | | |
Patient ID

S | | | | |
Screening ID

Form	Version
URCC 13059 - GAP 70+ Tumor and Treatment Characteristics	Amd2

Patient Initials

● Screening

1. Did the patient give permission to collect Medicare claim data, per consent? ☐ No ☐ Yes

Medicare Beneficiary #

1a. Does the patient have supplemental insurance? ☐ No ☐ Yes

1b. If yes, please fill out name of insurance and number below:

Name of Policy	Identification Number

2. What is the patient's current cancer diagnosis? *(Please mark an X in all that apply)*

☐ Adrenal	☐ Larynx	☐ Ovarian
☐ Anal	☐ Leukemia	☐ Pancreatic
☐ Bladder	☐ Lip & Oral cavity	☐ Pharyngeal
☐ Bone (e.g., osteosarcoma)	☐ Liver	☐ Prostate
☐ Breast Cancer	☐ Lung	☐ Rectal
☐ Brain Tumor	☐ Lymphoma	☐ Salivary
☐ Carcinoid (GI)	☐ Melanoma	☐ Sarcoma (not osteosarcoma)
☐ Cervical	☐ Merkel Cell	☐ Testicular
☐ Colon	☐ Mesothelioma	☐ Thyroid
☐ Endometrial	☐ Multiple Myeloma	☐ Unknown Primary
☐ Esophageal	☐ Nasal & Sinus	☐ Uterine
☐ Gastric (Stomach)	☐ Neuroblastoma	☐ Vaginal/Vulvar
☐ Kidney	☐ Neuroendocrine	
☐ Other, specify:		

3. What is the patient's disease stage?
(Please mark an X in the corresponding box and write as needed in the textbox provided)

☐ III ☐ IV ☐ Other, Specify:

4. Does the patient have a history of:

	No	Yes	If **Yes**, when? (Date mm/dd/yyyy)
4a. Prior venous thromboembolism (i.e. deep vein thrombosis or pulmonary embolism)	☐	☐	/ /
4b. Prior bleeding event that needed hospitalization or transfusion	☐	☐	/ /

5. Is chemotherapy part of patient's treatment plan? ☐ No ☐ Yes

6. Are other treatments part of patient's treatment plan?

6a. Monoclonal Antibodies ☐ No ☐ Yes

6b. Hormonal Treatments ☐ No ☐ Yes

6c. Oral Cancer Treatments (other than hormonal) ☐ No ☐ Yes

6d. Radiation Therapy Treatments ☐ No ☐ Yes

7. Planned Treatment Regimen:
Please include all cancer treatments being planned including chemotherapy, radiation therapy, monoclonal antibodies, hormonal treatments, or any oral treatments (such as vascular endothelial growth factor or tyrosine kinase inhibitors).

Dose Frequency					
	QD- Once Daily	**TID**- Three times a day	**qwk**- every week	**q3wk**- every 3 weeks	**qmnth**- every month
	BID- Twice Daily	**QID**- Four times a day	**q2wk**- every 2 weeks	**q4wk**- every 4 weeks	

	Agent Name	Dose	Fill in One Box	Freq.	Comment
1.			☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:		
2.			☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:		
3.			☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:		
4.			☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:		
5.			☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:		
6.			☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:		
7.			☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:		

8. Are White Blood Cell growth factors part of the patient's treatment plan? ☐ No ☐ Yes

9. Is Erythropoietic stimulating agent part of the patient's treatment plan? ☐ No ☐ Yes

1					Form	Version		
Patient ID					**URCC 13059 - GAP 70+** Cancer Treatment History	Amd2	Patient Initials	

● Baseline

CANCER Type

Date the patient was first diagnosed with advanced cancer: ☐☐ / ☐☐ / ☐☐

Surgery for advanced cancer within the last year (not biopsies): ○ Yes ○ No

If Yes, date of Surgery? ☐☐ / ☐☐ / ☐☐

Previous Surgery Type for Advanced Cancer:

1.

2.

Chemotherapy for advanced cancer within the last year: ○ Yes ○ No

If Yes, date of most recent Chemotherapy? ☐☐ / ☐☐ / ☐☐

Number of Previous Chemotherapy Regimens for advanced cancer within the last year: ☐☐☐

Previous Chemotherapy Agents for advanced cancer within the last year:

1.

2.

3.

Radiation Therapy for advanced cancer within the last year: ○ Yes ○ No

If Yes, date of most recent Radiation Therapy? ☐☐ / ☐☐ / ☐☐

Previous Radiation Treatment Fields for Advanced Cancer:

1.

2.

1 | | | | |

Patient ID

Form	Version
URCC 13059 - GAP 70+ Cancer Treatment Dosage Form	Amd2

| | | |

Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up

Instructions: Please complete **a new Cancer Treatment Dosage Form for each treatment cycle for advanced cancer** through the 3 month follow-up. Include ALL medical treatments the patient is receiving including intravenous chemotherapy, oral chemotherapy, monoclonal antibodies, oral cancer drugs (e.g., erlotinib), and hormonal treatments.
Note: You will need to complete a new Cancer Treatment Dosage Form for each treatment cycle through the 6 month follow-up ONLY for those patients who have **remained on the same drug regimen throughout the study (use separate 6 month cancer treatment dosage form).**
Cycle 1 should be compared to the original plan outlined in the Tumor and Treatment Characteristics Form, all other cycle regimens are compared to the previous cycle and any changes in the treatment plan and the reason for this should be noted on this form.

1. Is the patient currently receiving chemotherapy for their cancer? ☐ No ☐ Yes

2. For this cycle what is the current treatment plan? Cycle # ☐

a. Start Date (mm/dd/yy): ☐☐ / ☐☐ / ☐☐

b. Cycle Length: ☐ Days ☐ Weeks

c. Body Surface Area: ☐ m^2 Weight: ☐☐☐ lbs

d. Is the current treatment different when compared to a previous cycle? [NOTE: If cycle 1, does the current plan differ from the original treatment plan noted on the *Tumor and Treatment Characteristics Form*] ☐ No ☐ Yes

Dose Modifications		**Dose Modification Reason**		
1 = Dose held	5 = Drug increased in error	1 = Toxicity	6 = Disease progression	9a.
2 = Dose delayed	6 = Drug given too early	2 = Patient declined/non-compliant (not due to toxicity)	7 = Patient preference	
3 = Dose reduced	7 = Drug escalation	3 = Scheduling issue	8 = Patient deceased	9b.
4 = Drug discontinued	8 = Dose missed	4 = Dosing error	9 = Other, Specify:	
		5 = Alternative therapy used		9c.

Dose Frequency		
QD - once daily	qwk - every week	PRN - as needed
BID - twice daily	q2wk - every 2 weeks	OTH - other
TID - three times a day	q3wk - every 3 weeks	
QID - four times a day	q4wk - every 4 weeks	
	qmnth- every month	

1 ☐☐☐☐

Patient ID

Form	Version
URCC 13059 - GAP 70+ Cancer Treatment Dosage Form	Amd2

☐☐☐

Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up

Please remember to enter toxicity side effects on the Toxicity Outcomes Form and grade the toxicity. The start and end dates should reflect the dates the drugs are actually given, not necessarily the cycle length.

Agent Name	Planned Dose	Planned Dose Units	Actual Total Dose Given (mg)	Freq.	Start Date (mm/dd/yy) ACTUAL	End Date (mm/dd/yy) ACTUAL	Dose Modifications During Tx	Dose Modification Reason
1.		☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:			☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐☐	☐☐
2.		☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:			☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐☐	☐☐
3.		☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:			☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐☐	☐☐
4.		☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:			☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐☐	☐☐
5.		☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:			☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐☐	☐☐
6.		☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:			☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐☐	☐☐

NOTE: If supportive care has changed please update the supportive care log.

1				

Patient ID

Form	Version
URCC 13059 - GAP 70+ Cancer Treatment Dosage Form	Amd2

Patient Initials

● 6 Month Follow-up

Instructions: Please complete **a new Cancer Treatment Dosage Form for each treatment cycle for advanced cancer** through the 6 month follow-up **ONLY** for those patients who have **remained on the same drug regimen throughout the study (even if dosage has changed).** Include ALL medical treatments the patient is receiving including intravenous chemotherapy, oral chemotherapy, monoclonal antibodies, oral cancer drugs (e.g., erlotinib), and hormonal treatments.

1. Is the patient currently receiving any chemotherapy for their cancer? ☐ No ☐ Yes

2. For this cycle what is the current treatment plan? Cycle # ☐

a. Start Date (mm/dd/yy): ☐☐ / ☐☐ / ☐☐

b. Cycle Length: ☐ Days ☐ Weeks

c. Body Surface Area: ☐ m^2 Weight: ☐☐☐ lbs

d. Is the current treatment different when compared to a previous cycle? ☐ No ☐ Yes

Dose Modifications		**Dose Modification Reason**		
1 = Dose held	5 = Drug increased in error	1 = Toxicity	6 = Disease progression	9a.
2 = Dose delayed	6 = Drug given too early	2 = Patient declined/non-compliant (not due to toxicity)	7 = Patient preference	
3 = Dose reduced	7 = Drug escalation	3 = Scheduling issue	8 = Patient deceased	9b.
4 = Drug discontinued	8 = Dose missed	4 = Dosing error	9 = Other, Specify:	
		5 = Alternative therapy used		9c.

Dose Frequency		
QD - once daily	qwk - every week	PRN - as needed
BID - twice daily	q2wk - every 2 weeks	OTH - other
TID - three times a day	q3wk - every 3 weeks	
QID - four times a day	q4wk - every 4 weeks	
	qmnth- every month	

1 ☐☐☐☐

Patient ID

Form	Version
URCC 13059 - GAP 70+ Cancer Treatment Dosage Form	Amd2

☐☐☐

Patient Initials

● 6 Month Follow-up

Please remember to enter toxicity side effects on the Toxicity Outcomes Form and grade the toxicity. The start and end dates should reflect the dates the drugs are actually given, not necessarily the cycle length.

Agent Name	Planned Dose	Planned Dose Units	Actual Total Dose Given (mg)	Freq.	Start Date (mm/dd/yy) ACTUAL	End Date (mm/dd/yy) ACTUAL	Dose Modifications During Tx	Dose Modification Reason
1.		☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:			☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐☐	☐☐
2.		☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:			☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐☐	☐☐
3.		☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:			☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐☐	☐☐
4.		☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:			☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐☐	☐☐
5.		☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:			☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐☐	☐☐
6.		☐ mg/m^2 ☐ AUC ☐ mg/kg ☐ Other:			☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐☐	☐☐

NOTE: If supportive care has changed please update the supportive care log.

Patient ID	Form	Version	Patient Initials
1	**URCC 13059 - GAP 70+** Toxicity Outcomes Hematologic and Non-Hematologic	Amd2	

○ 4-6 Weeks ○ 3 Month Follow-up

Toxicity Outcomes are to be updated and submitted at each assessment.

Instructions: Please complete a **new toxicity outcome form for each treatment cycle for advanced cancer through the 3 month follow-up visit.** Include **ALL Grade 2-5** CTCAEs (using version 4.0) that the patient is experiencing, onset date, and outcome. For any lab related toxicities, include a copy of the laboratory report. If a toxicity's grade changes during a cycle, please enter a new line noting the toxicity, date and new grade level. If treatment was discontinued, please capture toxicities for 1 month after last treatment.

Note: You will need to complete a new toxicity outcome form for each treatment cycle through the 6 month follow-up ONLY for those patients who have remained on the same drug regimen throughout the study (use separate 6 month toxicity outcome form).

1. Cycle Number: ☐ Start Date (mm/dd/yy): ☐☐ / ☐☐ / ☐☐

2. ☐ Check box if no toxicities were reported with this cycle.

Toxicity	Did this toxicity lead to any outcomes listed below?			
1.	**Hospitalization** ☐ No ☐ Yes	**Date Onset** ☐☐ / ☐☐ / ☐☐	**Dose Reduction** ☐ No ☐ Yes	**Date Onset** ☐☐ / ☐☐ / ☐☐
Lab Date/ Est. ONSET Date (mm/dd/yy) ☐☐ / ☐☐ / ☐☐ **Grade** ☐	**Hospice** ☐ No ☐ Yes	**Date Onset** ☐☐ / ☐☐ / ☐☐	**Dose Hold/Delay** ☐ No ☐ Yes	**Date Onset** ☐☐ / ☐☐ / ☐☐
	Transfusion ☐ No ☐ Yes	**Date Onset** ☐☐ / ☐☐ / ☐☐	**D/C Treatment Permanently** ☐ No ☐ Yes	**Date Onset** ☐☐ / ☐☐ / ☐☐
2.	**Hospitalization** ☐ No ☐ Yes	**Date Onset** ☐☐ / ☐☐ / ☐☐	**Dose Reduction** ☐ No ☐ Yes	**Date Onset** ☐☐ / ☐☐ / ☐☐
Lab Date/ Est. ONSET Date (mm/dd/yy) ☐☐ / ☐☐ / ☐☐ **Grade** ☐	**Hospice** ☐ No ☐ Yes	**Date Onset** ☐☐ / ☐☐ / ☐☐	**Dose Hold/Delay** ☐ No ☐ Yes	**Date Onset** ☐☐ / ☐☐ / ☐☐
	Transfusion ☐ No ☐ Yes	**Date Onset** ☐☐ / ☐☐ / ☐☐	**D/C Treatment Permanently** ☐ No ☐ Yes	**Date Onset** ☐☐ / ☐☐ / ☐☐

1 | | | | |

Patient ID

Form	Version
URCC 13059 - GAP 70+ Toxicity Outcomes Hematologic and Non-Hematologic	Amd2

Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up

Toxicity Outcomes are to be updated and submitted at each assessment.

Toxicity	Did this toxicity lead to any outcomes listed below?	
3.	**Hospitalization** ☐ No ☐ Yes **Date Onset** / /	**Dose Reduction** ☐ No ☐ Yes **Date Onset** / /
	Hospice ☐ No ☐ Yes **Date Onset** / /	**Dose Hold/Delay** ☐ No ☐ Yes **Date Onset** / /
Lab Date/ Est. ONSET Date (mm/dd/yy) / / **Grade**	**Transfusion** ☐ No ☐ Yes **Date Onset** / /	**D/C Treatment Permanently** ☐ No ☐ Yes **Date Onset** / /
4.	**Hospitalization** ☐ No ☐ Yes **Date Onset** / /	**Dose Reduction** ☐ No ☐ Yes **Date Onset** / /
	Hospice ☐ No ☐ Yes **Date Onset** / /	**Dose Hold/Delay** ☐ No ☐ Yes **Date Onset** / /
Lab Date/ Est. ONSET Date (mm/dd/yy) / / **Grade**	**Transfusion** ☐ No ☐ Yes **Date Onset** / /	**D/C Treatment Permanently** ☐ No ☐ Yes **Date Onset** / /
5.	**Hospitalization** ☐ No ☐ Yes **Date Onset** / /	**Dose Reduction** ☐ No ☐ Yes **Date Onset** / /
	Hospice ☐ No ☐ Yes **Date Onset** / /	**Dose Hold/Delay** ☐ No ☐ Yes **Date Onset** / /
Lab Date/ Est. ONSET Date (mm/dd/yy) / / **Grade**	**Transfusion** ☐ No ☐ Yes **Date Onset** / /	**D/C Treatment Permanently** ☐ No ☐ Yes **Date Onset** / /

1				

Patient ID

Form	Version
URCC 13059 - GAP 70+ Toxicity Outcomes Hematologic and Non-Hematologic	Amd2

Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up

Toxicity Outcomes are to be updated and submitted at each assessment.

Toxicity	Did this toxicity lead to any outcomes listed below?	
6.	**Hospitalization** ☐ No ☐ Yes **Date Onset** / /	**Dose Reduction** ☐ No ☐ Yes **Date Onset** / /
Lab Date/ Est. ONSET Date (mm/dd/yy) / / **Grade**	**Hospice** ☐ No ☐ Yes **Date Onset** / /	**Dose Hold/Delay** ☐ No ☐ Yes **Date Onset** / /
	Transfusion ☐ No ☐ Yes **Date Onset** / /	**D/C Treatment Permanently** ☐ No ☐ Yes **Date Onset** / /
7.	**Hospitalization** ☐ No ☐ Yes **Date Onset** / /	**Dose Reduction** ☐ No ☐ Yes **Date Onset** / /
Lab Date/ Est. ONSET Date (mm/dd/yy) / / **Grade**	**Hospice** ☐ No ☐ Yes **Date Onset** / /	**Dose Hold/Delay** ☐ No ☐ Yes **Date Onset** / /
	Transfusion ☐ No ☐ Yes **Date Onset** / /	**D/C Treatment Permanently** ☐ No ☐ Yes **Date Onset** / /
8.	**Hospitalization** ☐ No ☐ Yes **Date Onset** / /	**Dose Reduction** ☐ No ☐ Yes **Date Onset** / /
Lab Date/ Est. ONSET Date (mm/dd/yy) / / **Grade**	**Hospice** ☐ No ☐ Yes **Date Onset** / /	**Dose Hold/Delay** ☐ No ☐ Yes **Date Onset** / /
	Transfusion ☐ No ☐ Yes **Date Onset** / /	**D/C Treatment Permanently** ☐ No ☐ Yes **Date Onset** / /

Toxicity Outcomes are to be updated and submitted at each assessment.

Toxicity	Did this toxicity lead to any outcomes listed below?	
9. ☐	**Hospitalization** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐ **Hospice** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐ **Transfusion** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐	**Dose Reduction** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐ **Dose Hold/Delay** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐ **D/C Treatment Permanently** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐
Lab Date/ Est. ONSET Date (mm/dd/yy) ☐☐/☐☐/☐☐ **Grade** ☐		
10. ☐	**Hospitalization** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐ **Hospice** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐ **Transfusion** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐	**Dose Reduction** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐ **Dose Hold/Delay** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐ **D/C Treatment Permanently** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐
Lab Date/ Est. ONSET Date (mm/dd/yy) ☐☐/☐☐/☐☐ **Grade** ☐		

If more than 10 toxicities (hematologic and non-hematologic) were reported during this cycle, please use additional pages as necessary.

1				

Patient ID

Form	Version
URCC 13059 - GAP 70+ Toxicity Outcomes Hematologic and Non-Hematologic	Amd2

Patient Initials

● 6 Month Follow-up

Toxicity Outcomes are to be updated and submitted at each assessment.

Instructions: Please complete a **new toxicity outcome form for each treatment cycle for advanced cancer through the 6 month follow-up visit ONLY for those patients who have remained on the same drug regimen throughout the study (even if dosage has changed).** Include **ALL Grade 2-5** CTCAEs (using version 4.0) that the patient is experiencing, onset date, and outcome. For any lab related toxicities, include a copy of the laboratory report. If a toxicity's grade changes during a cycle, please enter a new line noting the toxicity, date and new grade level.

1. Cycle Number: ☐ Start Date (mm/dd/yy): ☐☐ / ☐☐ / ☐☐

2. ☐ Check box if no toxicities were reported with this cycle.

Toxicity	Did this toxicity lead to any outcomes listed below?	
1.	**Hospitalization** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐	**Dose Reduction** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐
Lab Date/ Est. ONSET Date (mm/dd/yy) ☐☐/☐☐/☐☐ **Grade** ☐	**Hospice** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐	**Dose Hold/Delay** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐
	Transfusion ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐	**D/C Treatment Permanently** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐
2.	**Hospitalization** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐	**Dose Reduction** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐
Lab Date/ Est. ONSET Date (mm/dd/yy) ☐☐/☐☐/☐☐ **Grade** ☐	**Hospice** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐	**Dose Hold/Delay** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐
	Transfusion ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐	**D/C Treatment Permanently** ☐ No ☐ Yes — **Date Onset** ☐☐/☐☐/☐☐

1 | | | | |

Patient ID

Form	Version
URCC 13059 - GAP 70+ Toxicity Outcomes Hematologic and Non-Hematologic	Amd2

Patient Initials

● 6 Month Follow-up

Toxicity Outcomes are to be updated and submitted at each assessment.

Toxicity	Did this toxicity lead to any outcomes listed below?	
3.	**Hospitalization** ☐ No ☐ Yes **Date Onset** / /	**Dose Reduction** ☐ No ☐ Yes **Date Onset** / /
Lab Date/ Est. ONSET Date (mm/dd/yy) / / **Grade**	**Hospice** ☐ No ☐ Yes **Date Onset** / /	**Dose Hold/Delay** ☐ No ☐ Yes **Date Onset** / /
	Transfusion ☐ No ☐ Yes **Date Onset** / /	**D/C Treatment Permanently** ☐ No ☐ Yes **Date Onset** / /
4.	**Hospitalization** ☐ No ☐ Yes **Date Onset** / /	**Dose Reduction** ☐ No ☐ Yes **Date Onset** / /
Lab Date/ Est. ONSET Date (mm/dd/yy) / / **Grade**	**Hospice** ☐ No ☐ Yes **Date Onset** / /	**Dose Hold/Delay** ☐ No ☐ Yes **Date Onset** / /
	Transfusion ☐ No ☐ Yes **Date Onset** / /	**D/C Treatment Permanently** ☐ No ☐ Yes **Date Onset** / /
5.	**Hospitalization** ☐ No ☐ Yes **Date Onset** / /	**Dose Reduction** ☐ No ☐ Yes **Date Onset** / /
Lab Date/ Est. ONSET Date (mm/dd/yy) / / **Grade**	**Hospice** ☐ No ☐ Yes **Date Onset** / /	**Dose Hold/Delay** ☐ No ☐ Yes **Date Onset** / /
	Transfusion ☐ No ☐ Yes **Date Onset** / /	**D/C Treatment Permanently** ☐ No ☐ Yes **Date Onset** / /

1				

Patient ID

Form	Version
URCC 13059 - GAP 70+ Toxicity Outcomes Hematologic and Non-Hematologic	Amd2

Patient Initials

● 6 Month Follow-up

Toxicity Outcomes are to be updated and submitted at each assessment.

Toxicity	Did this toxicity lead to any outcomes listed below?	
6.	**Hospitalization** ☐ No ☐ Yes — **Date Onset** / /	**Dose Reduction** ☐ No ☐ Yes — **Date Onset** / /
Lab Date/ Est. ONSET Date (mm/dd/yy) / / **Grade**	**Hospice** ☐ No ☐ Yes — **Date Onset** / /	**Dose Hold/Delay** ☐ No ☐ Yes — **Date Onset** / /
	Transfusion ☐ No ☐ Yes — **Date Onset** / /	**D/C Treatment Permanently** ☐ No ☐ Yes — **Date Onset** / /
7.	**Hospitalization** ☐ No ☐ Yes — **Date Onset** / /	**Dose Reduction** ☐ No ☐ Yes — **Date Onset** / /
Lab Date/ Est. ONSET Date (mm/dd/yy) / / **Grade**	**Hospice** ☐ No ☐ Yes — **Date Onset** / /	**Dose Hold/Delay** ☐ No ☐ Yes — **Date Onset** / /
	Transfusion ☐ No ☐ Yes — **Date Onset** / /	**D/C Treatment Permanently** ☐ No ☐ Yes — **Date Onset** / /
8.	**Hospitalization** ☐ No ☐ Yes — **Date Onset** / /	**Dose Reduction** ☐ No ☐ Yes — **Date Onset** / /
Lab Date/ Est. ONSET Date (mm/dd/yy) / / **Grade**	**Hospice** ☐ No ☐ Yes — **Date Onset** / /	**Dose Hold/Delay** ☐ No ☐ Yes — **Date Onset** / /
	Transfusion ☐ No ☐ Yes — **Date Onset** / /	**D/C Treatment Permanently** ☐ No ☐ Yes — **Date Onset** / /

1 ☐☐☐☐

Patient ID

Form	Version
URCC 13059 - GAP 70+ Toxicity Outcomes Hematologic and Non-Hematologic	Amd2

☐☐☐

Patient Initials

● 6 Month Follow-up

Toxicity Outcomes are to be updated and submitted at each assessment.

Toxicity	Did this toxicity lead to any outcomes listed below?	
9.	**Hospitalization** ☐ No ☐ Yes **Date Onset** ☐☐/☐☐/☐☐	**Dose Reduction** ☐ No ☐ Yes **Date Onset** ☐☐/☐☐/☐☐
Lab Date/ Est. ONSET Date (mm/dd/yy) ☐☐/☐☐/☐☐ **Grade** ☐	**Hospice** ☐ No ☐ Yes **Date Onset** ☐☐/☐☐/☐☐	**Dose Hold/Delay** ☐ No ☐ Yes **Date Onset** ☐☐/☐☐/☐☐
	Transfusion ☐ No ☐ Yes **Date Onset** ☐☐/☐☐/☐☐	**D/C Treatment Permanently** ☐ No ☐ Yes **Date Onset** ☐☐/☐☐/☐☐
10.	**Hospitalization** ☐ No ☐ Yes **Date Onset** ☐☐/☐☐/☐☐	**Dose Reduction** ☐ No ☐ Yes **Date Onset** ☐☐/☐☐/☐☐
Lab Date/ Est. ONSET Date (mm/dd/yy) ☐☐/☐☐/☐☐ **Grade** ☐	**Hospice** ☐ No ☐ Yes **Date Onset** ☐☐/☐☐/☐☐	**Dose Hold/Delay** ☐ No ☐ Yes **Date Onset** ☐☐/☐☐/☐☐
	Transfusion ☐ No ☐ Yes **Date Onset** ☐☐/☐☐/☐☐	**D/C Treatment Permanently** ☐ No ☐ Yes **Date Onset** ☐☐/☐☐/☐☐

If more than 10 toxicities (hematologic and non-hematologic) were reported during this cycle, please use additional pages as necessary.

1				

Patient ID

Form	Version
URCC 13059 - GAP 70+ Supportive Care Log	Amd2

Patient Initials

Supportive Care Log is to be updated and submitted at each assessment.

1. Does the current plan use White Blood Cell Growth Factors? ☐ No ☐ Yes (If yes, not needed on the log below)

2. Does the current plan use an Erythropoietic stimulating agent? ☐ No ☐ Yes (If yes, not needed on the log below)

3. Instructions: Please list all cancer treatment supportive care agents below. Review and update Supportive Care medications at each visit up to the last time point for which toxicity information is being collected (3 or 6 months).

Dose Units			**Dose Frequency**		
g = gram gr = grain gtt = drop mcg = microgram mcL = microliter	mg = milligram mL = milliliter oz = ounce SPY = spray/squirt supp = suppository	TBSP = tablespoon tsp = teaspoon OTH = other, specify	BID - twice daily TID - three times a day QID - four times a day q2h - every 2 hours q4h - every 4 hours qmth - monthly	q4h - every 4 hours q6h - every 6 hours q8h - every 8 hours QAM - one dose in morning	QPM - one dose in evening QD - once daily HS - at bedtime PRN - as needed OTH - other

Supportive Care Drug Name	**Dose Given w/Units**	**Freq.**	**Start Date** (mm/dd/yy) **ACTUAL**	**End Date** (mm/dd/yy) **ACTUAL**
1.	**Dose:** **Units:**		/ /	/ /
2.	**Dose:** **Units:**		/ /	/ /
3.	**Dose:** **Units:**		/ /	/ /

1 | | | | |

Patient ID

Form	Version
URCC 13059 - GAP 70+ Supportive Care Log	Amd2

| | | |

Patient Initials

Supportive Care Drug Name	Dose Given w/Units	Freq.	Start Date (mm/dd/yy) ACTUAL	End Date (mm/dd/yy) ACTUAL
4.	Dose: Units:		/ /	/ /
5.	Dose: Units:		/ /	/ /
6.	Dose: Units:		/ /	/ /
7.	Dose: Units:		/ /	/ /
8.	Dose: Units:		/ /	/ /
9.	Dose: Units:		/ /	/ /
10.	Dose: Units:		/ /	/ /

If there are more than 10 supportive care drugs, please use additional pages as necessary.

1				

Patient ID

S				

Screening ID

Form	Version
URCC 13059 - GAP 70+ Physician Rated KPS	Amd2

Patient Initials

● Screening

1. Karnofsky Performance Status | | | | %

DEFINITION	%	CRITERIA
Able to carry on normal activity and to work; no special care needed.	100	Normal no complaints; no evidence of disease.
	90	Able to carry on normal activity; minor signs or symptoms of disease.
	80	Normal activity with effort; some signs or symptoms of disease.
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed.	70	Cares for self; unable to carry on normal activity or to do active work.
	60	Requires occasional assistance, but is able to care for most of his personal needs.
	50	Requires considerable assistance and frequent medical care.
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.	40	Disabled; requires special care and assistance.
	30	Severely disabled; hospital admission is indicated although death not imminent.
	20	Very sick; hospital admission necessary; active supportive treatment necessary.
	10	Moribund; fatal processes progressing rapidly.
	0	Dead.

1					Form	Version			
Patient ID					**URCC 13059 - GAP 70+** Physician Rated KPS	Amd2			Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

1. Karnofsky Performance Status ☐☐☐%

DEFINITION	%	CRITERIA
Able to carry on normal activity and to work; no special care needed.	100	Normal no complaints; no evidence of disease.
	90	Able to carry on normal activity; minor signs or symptoms of disease.
	80	Normal activity with effort; some signs or symptoms of disease.
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed.	70	Cares for self; unable to carry on normal activity or to do active work.
	60	Requires occasional assistance, but is able to care for most of his personal needs.
	50	Requires considerable assistance and frequent medical care.
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.	40	Disabled; requires special care and assistance.
	30	Severely disabled; hospital admission is indicated although death not imminent.
	20	Very sick; hospital admission necessary; active supportive treatment necessary.
	10	Moribund; fatal processes progressing rapidly.
	0	Dead.

1				

Patient ID

S				

Screening ID

Form	Version
URCC 13059 - GAP 70+ Labs	Amd2

Patient Initials

● Screening

Instructions: Please record the most recent laboratory values.

Date Drawn:	☐☐ / ☐☐ / ☐☐☐☐
1. Creatinine:	☐☐.☐☐ **mg/dl**
2. Creatinine Clearance:	☐☐.☐☐ **ml/min**

2a. Is the creatinine clearance or GFR < 60 ml/min?

☐ **No** ☐ **Yes** *(If **Yes**, patient is **impaired** per GA scoring)*

3. Albumin:	☐☐.☐☐ **g/100ml**

1				

Patient ID

Form	Version
URCC 13059 - GAP 70+ Polypharmacy Log	Amd2

S				

Screening ID

Patient Initials

Polypharmacy Log is to be updated and submitted at each assessment.

Instructions: Review and update medications at each visit up to the 6 month follow-up visit.

Dose Units			**Route**		**Dose Frequency**		
g = gram gr = grain gtt = drop mcg = microgram mcL = microliter	mg = milligram mL = milliliter oz = ounce SPY = spray/squirt supp = suppository	TBSP = tablespoon tsp = teaspoon UNK = unknown	IM - intramuscular IN - intranasal INH - inhaled IT - intrathecally IV - intravenous	PO - oral SC - subcutaneous TOP - topical OTIC - by ear OTH - other, specify	BID - twice daily TID - three times a day QID - four times a day q2h - every 2 hours q4h - every 4 hours qmth - monthly	q6h - every 6 hours q8h - every 8 hours QAM - one dose in morning QPM - one dose in evening	QD - once daily HS - at bedtime PRN - as needed OTH - other UNK - unknown

1. Please list all medications in the table below.(Only the medications that are taken regularly count toward polypharmacy impairment)
+If the exact dates are not known please check "est" for estimate or "unk" for unknown.
* Presciptions also available over the counter do not qualify as a prescription medication. (These do not count toward polypharmacy impairment)

Medication Name	Indication	Dose w/Units	Freq. Route	Start/End Date+ (mm/dd/yy)	Does the patient take this regularly or PRN (as needed)	Did the patient take this in the last 2 weeks?	Is this a Prescription medication?*	High Risk? (See Pol. High Risk Drug Review)
1.		Dose: Units:	Freq: Route:	Est ☐ Unk ☐ Start Date: / / End Date: / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
2.		Dose: Units:	Freq: Route:	Est ☐ Unk ☐ Start Date: / / End Date: / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
3.		Dose: Units:	Freq: Route:	Est ☐ Unk ☐ Start Date: / / End Date: / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

1 | | | | |
Patient ID

Form	Version
URCC 13059 - GAP 70+ Polypharmacy Log	Amd2

S | | | | |
Screening ID

| | | |
Patient Initials

Polypharmacy Log is to be updated and submitted at each assessment.

Medication Name	Indication	Dose w/Units	Freq. Route	Start/End Date+ (mm/dd/yy)	Does the patient take this Regularly or PRN (as needed)	Did the patient take this in the last 2 weeks?	Is this a Prescription Medication?*	High Risk? (See Pol. High Risk Drug Review)
4.		Dose: Units:	Freq: Route:	Est ☐ Unk ☐ Start Date: / / End Date: / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
5.		Dose: Units:	Freq: Route:	Est ☐ Unk ☐ Start Date: / / End Date: / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
6.		Dose: Units:	Freq: Route:	Est ☐ Unk ☐ Start Date: / / End Date: / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
7.		Dose: Units:	Freq: Route:	Est ☐ Unk ☐ Start Date: / / End Date: / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
8.		Dose: Units:	Freq: Route:	Est ☐ Unk ☐ Start Date: / / End Date: / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

1 | | | | |
Patient ID

Form	Version
URCC 13059 - GAP 70+ Polypharmacy Log	Amd2

S | | | | |
Screening ID

| | | |
Patient Initials

Polypharmacy Log is to be updated and submitted at each assessment.

Medication Name	Indication	Dose w/Units	Freq. Route	Start/End Date+ (mm/dd/yy)	Does the patient take this Regularly or PRN (as needed)	Did the patient take this in the last 2 weeks?	Is this a Prescription Medication?	High Risk? (See Pol. High Risk Drug Review)
9.		**Dose:** **Units:**	Freq. Route	Est ☐ Unk ☐ **Start Date:** / / **End Date:** / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
10.		**Dose:** **Units:**	Freq. Route	Est ☐ Unk ☐ **Start Date:** / / **End Date:** / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
11.		**Dose:** **Units:**	Freq. Route	Est ☐ Unk ☐ **Start Date:** / / **End Date:** / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
12.		**Dose:** **Units:**	Freq. Route	Est ☐ Unk ☐ **Start Date:** / / **End Date:** / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
13.		**Dose:** **Units:**	Freq. Route	Est ☐ Unk ☐ **Start Date:** / / **End Date:** / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

1 | | | | |
Patient ID

Form	Version
URCC 13059 - GAP 70+ Polypharmacy Log	Amd2

S | | | | |
Screening ID

| | | |
Patient Initials

Polypharmacy Log is to be updated and submitted at each assessment.

Medication Name	Indication	Dose w/Units	Freq. Route	Start/End Date+ (mm/dd/yy)	Does the patient take this Regularly or PRN (as needed)	Did the patient take this in the last 2 weeks?	Is this a Prescription Medication?	High Risk? (See Pol. High Risk Drug Review)
14.		Dose: Units:	Freq. Route	Est ☐ Unk ☐ Start Date: / / End Date: / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
15.		Dose: Units:	Freq. Route	Est ☐ Unk ☐ Start Date: / / End Date: / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
16.		Dose: Units:	Freq. Route	Est ☐ Unk ☐ Start Date: / / End Date: / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
17.		Dose: Units:	Freq. Route	Est ☐ Unk ☐ Start Date: / / End Date: / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
18.		Dose: Units:	Freq. Route	Est ☐ Unk ☐ Start Date: / / End Date: / /	☐ Regularly ☐ PRN	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

1				

Patient ID

S				

Screening ID

Form	Version
URCC 13059 - GAP 70+ Polypharmacy High Risk Drug Review	Amd2

Patient Initials

● Screening

1. Please check the box with an **"X"** indicating whether the patient is taking any of the following medications.

Medications (Trade Name)/Medication Class - High Risk		**No**	**Yes**
a.	Alprazolam (Xanax)	☐	☐
b.	Amitriptyline (alone or in a combination pill)	☐	☐
c.	Butalbital (alone or in a combination pill)	☐	☐
d.	Chlordiazepoxide (alone or in a combination pill)	☐	☐
e.	Chlorpropamide	☐	☐
f.	Clomipramine	☐	☐
g.	Clonazepam (Klonopin)	☐	☐
h.	Clorazepate	☐	☐
i.	Diazepam (Valium)	☐	☐
j.	Digoxin	☐	☐
k.	Doxepin	☐	☐
l.	Estazolam	☐	☐
m.	Flurazepam	☐	☐
n.	Glyburide	☐	☐
o.	Growth Hormone	☐	☐
p.	Hydroxyzine (Atarax)	☐	☐
q.	Imipramine	☐	☐
r.	Ketorolac	☐	☐
s.	Lorazepam (Ativan)	☐	☐
t.	Meperidine	☐	☐
u.	Oxazepam	☐	☐
v.	Phenobarbital	☐	☐
w.	Promethazine (Phenergan)	☐	☐
x.	Quazepam	☐	☐
y.	Temazepam	☐	☐
z.	Triazolam	☐	☐
aa.	Trimipramine	☐	☐

2. Please check the box with an **"X"** indicating whether the patient is taking any of the following medications or medication class.

	Medications (Trade Name)/Medication Class	No	Yes
a.	Anticonvulsants (medicines for seizures)	☐	☐
b.	Blood Thinners (anticoagulants)	☐	☐
c.	Diabetes medications, including pills or insulin	☐	☐

1				

Patient ID

S				

Screening ID

Form	Version
URCC 13059 - GAP Blessed Orientation Memory Concentration Test (BOMC)	Amd2

Patient Initials

● Screening

"Now I would like to ask you some questions to check your memory and concentration. Some of them may be easy and some of them may be hard."	**Max Errors**	**Errors**	**x Weight**	**Score**
1. "What year is it now"? _____ Correct = 0 errors Incorrect = 1 error	1 max	☐	x 4 =	☐
2. "What month is it now"? _____ Correct = 0 errors Incorrect = 1 error	1 max	☐	x 3 =	☐

"Please repeat this name and address after me."

"John Brown, 42 Market Street, Chicago"

"Good, now remember that name and address because I will ask you for it in a few minutes."

3. "Tell me what time it is without looking at your watch." If response is vague, prompt for hour and minute. Scored as correct if time given is within +/- 1 hour. Correct = 0 errors Incorrect = 1 error	1 max	☐	x 3 =	☐
4. "Count aloud backwards from 20 to 1." If subject starts counting forward or forgets the task, repeat instructions and score one error. 20, 19, 18, 17, 16, 15, 14, 13, 12, 11, 10, 9, 8, 7, 6, 5, 4, 3, 2, 1 Correct = 0 errors Incorrect = 1 or 2 errors	2 max	☐	x 2 =	☐
5. "Say the months in reverse order, starting from December all the way down to January." If subject starts with January, clarifications allowed once without counting as an error. D N O S A JL JN MY AP MR F J Correct = 0 errors Incorrect = 1 or 2 errors	2 max	☐	x 2 =	☐
6. "Repeat the name and address I asked you to remember." [John] [Brown] [42] [Market St] [Chicago] (1 error) (1 error) (1 error) (1 error) (1 error) (The word 'Street' is not scored) Correct = 0 errors Incorrect = 1 to 5 errors	5 max	☐	x 2 =	☐☐ + _____ **Sum Total =** ☐☐

Notify study physician if total score is ≥ 11

1				

Patient ID

S				

Screening ID

Form	Version
URCC 13059 - GAP 70+ MINI-COG	Amd2

Patient Initials

● Screening

Instructions for Administration	Scoring/Special Instructions
1. Ask the patient to remember three unrelated words from one of the lists below. Ask the patient to repeat the words to ensure the learning was correct.	- Allow the patient three tries, then go to the next item. - Keep track of which list was used at each study visit. - Use a new list of words at following study visits

Mark an X to indicate which version was used in the box below.

Version 1	Version 2	Version 3	Version 4	Version 5	Version 6
Banana Sunrise Chair	Daughter Heaven Mountain	Village Kitchen Baby	River Nation Finger	Captain Garden Picture	Leader Season Table
☐	☐	☐	☐	☐	☐

2. Ask the patient to draw the face of a clock. After the numbers are drawn on the face, ask the patient to draw the hands to read 10 minutes after 11:00 (or 20 minutes after 8:00).	- A clock should not be visible to the patient during this task. - Use a blank piece of paper or a preprinted circle (next page). - Move to next step if clock is not complete within three minutes. - Correct response = all numbers placed in approx. the correct positions AND the hands pointing to 2 and 11 (or 4 and 8). - Scored as abnormal if patient declines to draw clock.
3. Record whether the Clock Drawing Test is normal or abnormal in the appropriate box to the right.	**Clock Drawing Test: Is the clock Normal or Abnormal?** Normal ☐ Abnormal ☐
4. Ask the patient to recall the three words from Step 1. Record the number of words correctly recalled in the appropriate box to the right.	**Word Recall: How many words did the patient recall?** 3 Words ☐ 1 to 2 Words ☐ 0 Words ☐

Scoring:

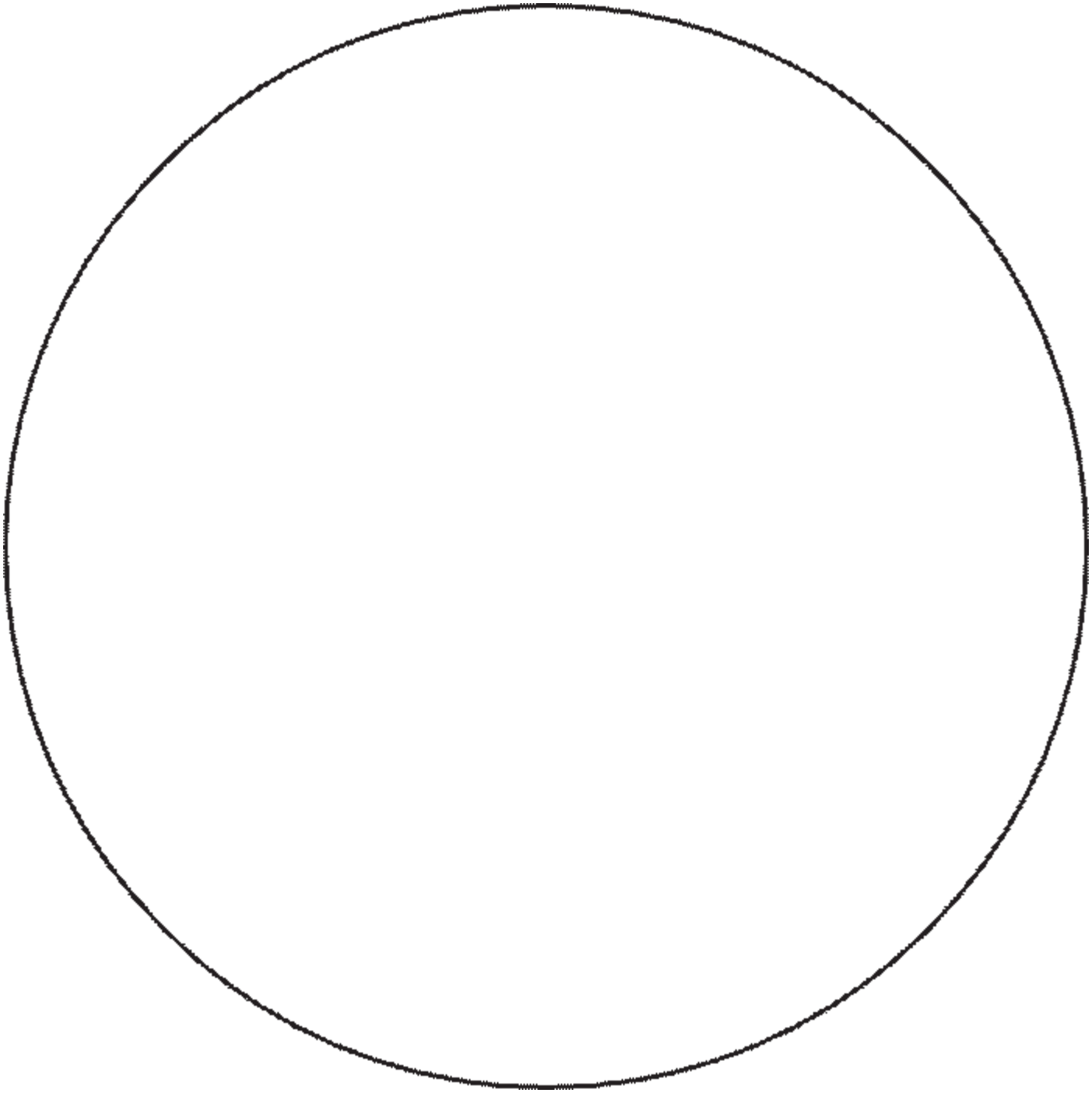
Word Recall	Clock Drawing Test	Impairment
3 Words	**N/A**	**Not Impaired** ☐
1 to 2 Words	**Normal**	**Not Impaired** ☐
1 to 2 Words	**Abnormal**	**Impaired** ☐
0 Words	**N/A**	**Impaired** ☐

Form	Version
URCC 13059 - GAP 70+ MINI-COG	Amd2

Patient Initials

● Screening

Clock Drawing Test (CDT)



1					Form	Version		
Patient ID					**URCC 13059 - GAP 70+** MINI-COG	Amd2		Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Instructions for Administration	**Scoring/Special Instructions**
1. Ask the patient to remember three unrelated words from one of the lists below. Ask the patient to repeat the words to ensure the learning was correct.	- Allow the patient three tries, then go to the next item. - Keep track of which list was used at each study visit. - Use a new list of words at following study visits

Mark an X to indicate which version was used in the box below.

Version 1	**Version 2**	**Version 3**	**Version 4**	**Version 5**	**Version 6**
Banana Sunrise Chair	Daughter Heaven Mountain	Village Kitchen Baby	River Nation Finger	Captain Garden Picture	Leader Season Table
☐	☐	☐	☐	☐	☐

2. Ask the patient to draw the face of a clock. After the numbers are drawn on the face, ask the patient to draw the hands to read 10 minutes after 11:00 (or 20 minutes after 8:00).	- A clock should not be visible to the patient during this task. - Use a blank piece of paper or a preprinted circle (next page). - Move to next step if clock is not complete within three minutes. - Correct response = all numbers placed in approx. the correct positions AND the hands pointing to 2 and 11 (or 4 and 8). - Scored as abnormal if patient declines to draw clock.
3. Record whether the Clock Drawing Test is normal or abnormal in the appropriate box to the right.	**Clock Drawing Test: Is the clock Normal or Abnormal?** Normal ☐ Abnormal ☐
4. Ask the patient to recall the three words from Step 1. Record the number of words correctly recalled in the appropriate box to the right.	**Word Recall: How many words did the patient recall?** 3 Words ☐ 1 to 2 Words ☐ 0 Words ☐

Scoring:

Word Recall	**Clock Drawing Test**	**Impairment**
3 Words	**N/A**	**Not Impaired** ☐
1 to 2 Words	**Normal**	**Not Impaired** ☐
1 to 2 Words	**Abnormal**	**Impaired** ☐
0 Words	**N/A**	**Impaired** ☐

1				

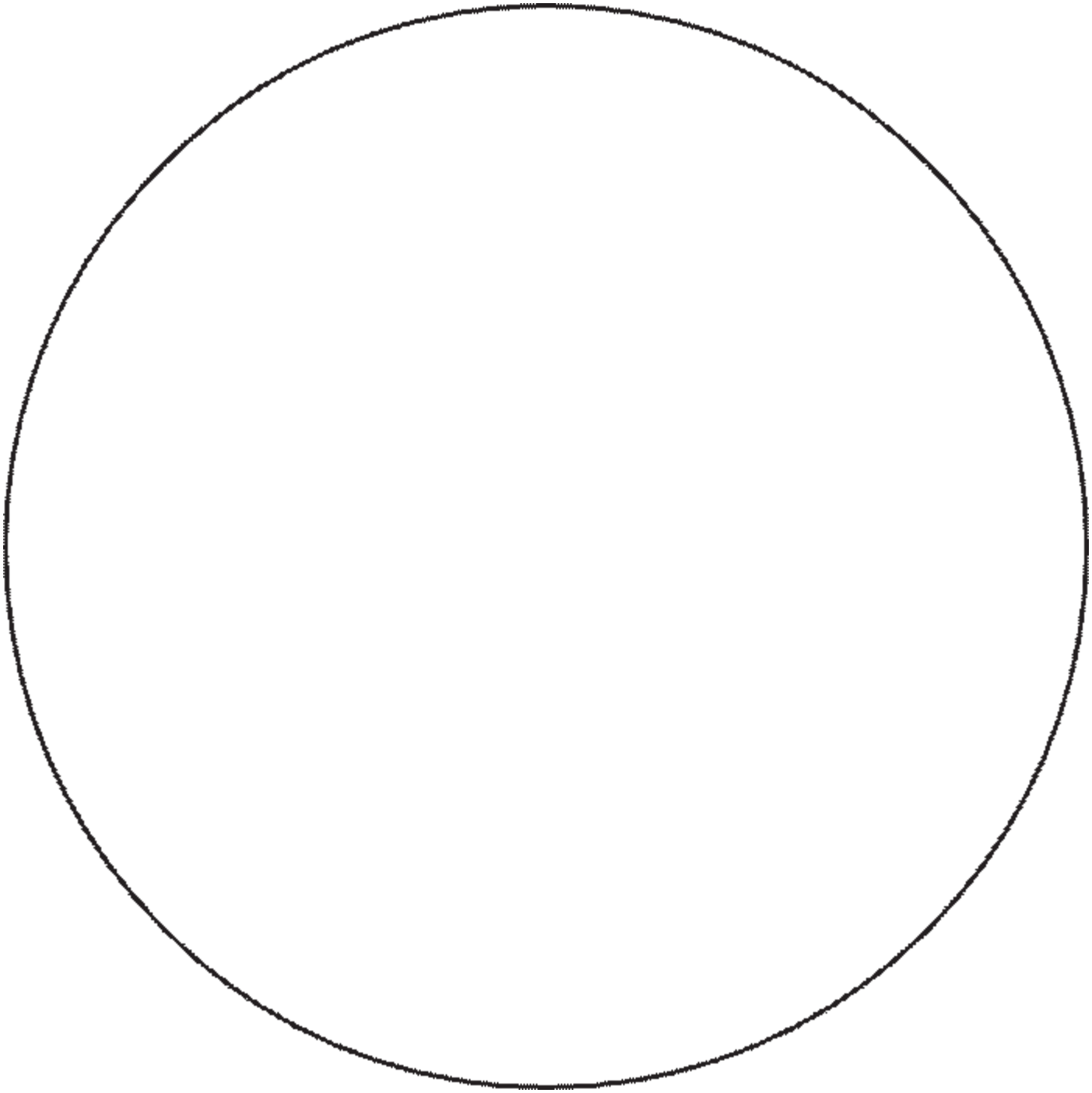
Patient ID

Form	Version
URCC 13059 - GAP 70+ MINI-COG	Amd2

Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Clock Drawing Test (CDT)



1 | | | | |

Patient ID

S | | | | |

Screening ID

Form	Version
URCC 13059 - GAP 70+ Nutritional Status & Mini Nutrition Assessment (MNA)	Amd2

| | | |

Patient Initials

● Screening

Instructions: Obtain patient's current height, current weight and past weight from the medical chart. If not in the chart, ask the patient what his/her weight was 6 months ago and then calculate the percentage of weight loss using the instructions below.

1. Patient's current height? (Use to calculate BMI on page 2) | | . | | inches

2. Patient's weight:

a. Weight approximately 6 months ago: | | | . | | pounds

b. Current weight: (Use to calculate BMI on page 2) | | | . | | pounds

c. Approximate weight loss over 6 months: **[a - b]** | | | . | | pounds

d. Percent weight loss: **[(c / a) x 100]** | | . | | %

Instructions: Complete by asking the patient the questions or reviewing the medical record and marking the appropriate boxes.

1. Food Intake:

"Have you eaten less than normal over the past three months?"
If so, "is this because of lack of appetite, chewing, or swallowing difficulties?"
If yes, "have you eaten much less than before or only a little less?"

☐ Large decrease in food intake *(0)*

☐ Moderate decrease in food intake *(1)*

☐ No decrease in food intake *(2)*

2. Involuntary weight loss during the last 3 months:

"Have you lost any weight without trying, over the last three months?"
If yes, "how much weight do you think you have lost? More or less than 6 pounds?"

☐ Weight loss greater than 3 kg (6.6lbs) *(0)*
☐ Does not know *(1)*
☐ Weight loss between 1 and 3 kg (2.2 and 6.6lbs) *(2)*
☐ No weight loss *(3)*

3. Mobility:

"How would you describe your current mobility?"
"Are you able to get out of a bed, chair, or wheelchair without the assistance of another person?"
If yes, "are you able to leave your home?"

☐ Bed or chair bound *(0)*
☐ Able to get out of bed/chair but does not go out *(1)*
☐ Goes out *(2) [Going out can be with or without assistance]*

4. Psychological stress or acute disease:
In completing this question, ask the patient first, if not possible then ask the caregiver/healthcare proxy and confirm in the medical record. Note: this can be due to any reason including cancer diagnosis.

"Have you ever been stressed and/or severely ill in the past 3 months?"

☐ Yes *(0)*
☐ No *(2)*

5. Neuropsychological problems:
In completing this question, ask the patient first, if not possible then ask the caregiver/healthcare proxy and confirm in the medical record.

"Do you have dementia and/or have you had prolonged or intense sadness?"

☐ Severe dementia or depression *(0)*
☐ Mild Dementia *(1)*
☐ No psychological problems *(2)*

6. Calculate Body Mass Index (BMI): ☐☐.☐

Use current height and weight from previous page. To calculate BMI use a BMI calculator or a web-based BMI calculator. If BMI calculator is unavailable refer to BMI index in study manual for GA.

7. Patient's Body Mass Index (BMI) Range:

☐ less than 19 *(0)*

☐ 19 to less than 21 *(1)*

☐ 21 to less than 23 *(2)*

☐ 23 or greater *(3)*

Total Score (max 14 points) ☐☐

SCORING:

- To score, add up the answer to each question, by summing the numbers in the parentheses.
- Only use the numbers in parentheses.

12-14 points = Normal nutritional status;
8-11 points = At risk of malnutrition;
0-7 points = Malnourished.

1				

Patient ID

S				

Screening ID

Form	Version
URCC 13059 - GAP 70+ Timed "Up and Go"	Amd2

Patient Initials

● Screening

Instructions:

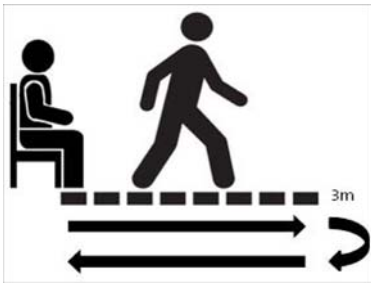
- Equipment: 2 standard arm chairs (seat height ~46cm, arm rest ~67cm), tape measure, tape or cones, and stop watch.
- The subject wears their regular footwear, may use any gait aid that they normally use during ambulation (if needed), but may not be assisted by another person. There is no time limit. They may stop and rest (but not sit down) if needed.
- Demonstrate the exercise for the subject by using the second arm chair so he/she understands the exercise.
- Begin the exercise with the subject sitting correctly (hips all of the way to the back of the seat) in a chair with arm rests. The chair should be stable and positioned such that it will not move when the subject moves from sit to stand. The subject is allowed to use the arm rests during the sit - stand and stand - sit movements.
- Place a piece of tape or other marker on the floor 3 meters away from the chair so that it is easily seen by the subject.
- Instructions to the subject: *"On the word GO you will stand up, walk to the line on the floor, turn around and walk back to the chair and sit down. Walk at a safe and comfortable pace."*
- Start timing on the word "GO" and stop timing when the subject is seated again in the chair.

Test:

What aid is the subject using?

☐ None ☐ Cane ☐ Walker ☐ Other (Specify): ☐

Timed Up and Go ☐☐☐.☐ seconds



If not attempted or failed, place an "X" in the appropriate box.

Tried but unable	Not attempted, patient felt unsafe	Not attempted, CRA judged patient as unsafe to perform
☐	☐	☐
Participant unable to understand instructions	**Participant declined**	**Other (Specify):** ☐
☐	☐	☐

1 ☐☐☐☐ Patient ID

S ☐☐☐☐ Screening ID

Form	Version
URCC 13059 - GAP 70+ Short Physical Performance Battery (SPPB)	Amd2

☐☐☐ Patient Initials

● Screening

Balance Test

1.A) Side-by-Side Stand (Feet together side-by-side)

☐ **Failed or Not attempted**
↳ **Reason:(Choose 1)**
- ☐ Unable for any reason
- ☐ Participant declined
- ☐ CRA judged unsafe to perform

☐ **Successful**
↳ **Seconds held** (≥ 10.00 sec.)**:** ☐☐.☐☐

- **Less than 10s** OR **Failed/Not attempted**: Mark **0,** go to **Gait Speed Test** (page 2)
- Held for **10s**: Mark **1,** go to the next test

1.A Points: ☐ *1pt max*

1.B) Semi-Tandem Stand *(Heel of one foot against side of big toe of the other)*

☐ **Failed or Not attempted**
↳ **Reason:(Choose 1)**
- ☐ Unable for any reason
- ☐ Participant declined
- ☐ CRA judged unsafe to perform

☐ **Successful**
↳ **Seconds held** (≥ 10.00 sec.)**:** ☐☐.☐☐

- **Less than 10s** OR **Failed/Not attempted**: Mark **0,** go to **Gait Speed Test** (page 2)
- Held for **10s**: Mark **1,** go to the next test

1.B Points: ☐ *1pt max*

1.C) Tandem Stand *(Heel of one foot in front of toes of the other)*

☐ **Failed or Not attempted**
↳ **Reason:(Choose 1)**
- ☐ Unable for any reason
- ☐ Participant declined
- ☐ CRA judged unsafe to perform

☐ **Successful**
↳ **Seconds held** (0-10.00 sec.)**:** ☐☐.☐☐

- **Less than 3s** OR **Failed/Not attempted**: Mark **0**
- Held for **3s** to less than **10s**: Mark **1**
- Held for **10s**: Mark **2**

1.C Points: ☐ *2pts max*

Please fill out Subtotal for the Balance Test, then go to Gait Speed Test on Next Page →

Balance Test Subtotal: ☐ *4pts max*

1 ☐☐☐☐ Patient ID

S ☐☐☐☐ Screening ID

Form	Version
URCC 13059 - GAP 70+ Short Physical Performance Battery (SPPB)	Amd2

☐☐☐ Patient Initials

● Screening

Gait Speed Test

2.A) Walk 1 (Measures the time required to walk 3 meters at a normal pace)

☐ **Failed or Not attempted**
↳ **Reason:(Choose 1)**
- ☐ Unable for any reason
- ☐ Participant declined
- ☐ CRA judged unsafe to perform

☐ **Successful**
↳ **Completion Time** (in seconds)**:** ☐☐.☐☐

- **If time equals 0s** OR **Failed/Not attempted**: Go to **Chair Stand Test** (page 3)
- If **successful**, fill in **Completion Time** and proceed to **2.B**

2.B) Walk 2 (Measures the time required to walk 3 meters at a normal pace)

☐ **Failed or Not attempted**
↳ **Reason:(Choose 1)**
- ☐ Unable for any reason
- ☐ Participant declined
- ☐ CRA judged unsafe to perform

☐ **Successful**
↳ **Completion Time** (in seconds)**:** ☐☐.☐☐

Aids used for either walk: ☐ None

☐ Cane ☐ Walker

☐ Other (Specify): _____

- **If time equals 0s** OR **Failed/Not attempted**: Go to **Chair Stand Test** (page 3)
- If **successful**, fill in **Completion Time** and proceed to **2.C**

2.C) Fastest Time of the two walks.

Points earned if time =

- ☐ 0.01 to 3.61 seconds (4 pts)
- ☐ 3.62 to 4.65 seconds (3 pts)
- ☐ 4.66 to 6.52 seconds (2 pts)
- ☐ ≥ 6.53 seconds (1 pt)
- ☐ Failed or not attempted (0 pts)

Fastest Time (of either walk)**:** ☐☐.☐☐

Gait Speed Test Subtotal: ☐ *4pts max*

Go to Chair Stand Test on Next Page →

1				

Patient ID

S				

Screening ID

Form	Version
URCC 13059 - GAP 70+ Short Physical Performance Battery (SPPB)	Amd2

Patient Initials

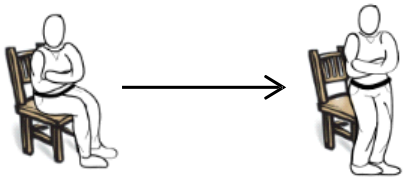
● Screening

Chair Stand Test

3.A) Pre-Test (Participants fold their arms across their chest and try to stand up once from a chair without using their arms)

☐ **Failed or Not attempted**
↳ **Reason:(Choose 1)**
- ☐ Unable for any reason
- ☐ Participant declined
- ☐ CRA judged unsafe to perform

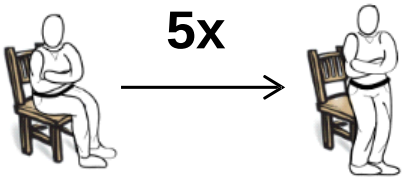
☐ **Successful**
↳ **Proceed to 3.B**



- **If Failed or Not attempted**: End Test
- If **successful**, proceed to **3.B**

3.B) 5 Repeats (Measures the time required to perform five rises from a chair to an upright position as fast as possible without the use of their arms) - Stop timer when patient stands upright 5th time

☐ **Failed or Not attempted**
↳ **Reason:(Choose 1)**
- ☐ Unable for any reason
- ☐ Participant declined
- ☐ CRA judged unsafe to perform



☐ **Successful**
↳ **Completion Time** (in seconds): ☐☐.☐☐

Points earned if time =

☐	0.01 to 11.19 seconds	(4 pts)
☐	11.20 to 13.69 seconds	(3 pts)
☐	13.70 to 16.69 seconds	(2 pts)
☐	16.70 to 60.00 seconds	(1 pt)
☐	≥ 60.01 seconds	(0 pts)
☐	0 seconds	(0 pts)

Subtotal Summation

Balance Test ☐ + **Gait Speed Test** ☐ + **Chair Stand Test** ☐ = ☐☐ **SPPB Total Sum** *(12 pts max)*

1					Form	Version		
Patient ID					**URCC 13059 - GAP 70+** Short Physical Performance Battery (SPPB)	Amd2	Patient Initials	

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Balance Test

1.A) Side-by-Side Stand (Feet together side-by-side)

☐ **Failed or Not attempted**
↳ **Reason:(Choose 1)**
- ☐ Unable for any reason
- ☐ Participant declined
- ☐ CRA judged unsafe to perform

☐ **Successful**
↳ **Seconds held** (≥ 10.00 sec.)**:** ☐☐.☐☐

- **Less than 10s** OR **Failed/Not attempted**: Mark **0,** go to **Gait Speed Test** (page 2)
- Held for **10s**: Mark **1,** go to the next test

1.A Points: ☐ *1pt max*

1.B) Semi-Tandem Stand *(Heel of one foot against side of big toe of the other)*

☐ **Failed or Not attempted**
↳ **Reason:(Choose 1)**
- ☐ Unable for any reason
- ☐ Participant declined
- ☐ CRA judged unsafe to perform

☐ **Successful**
↳ **Seconds held** (≥ 10.00 sec.)**:** ☐☐.☐☐

- **Less than 10s** OR **Failed/Not attempted**: Mark **0,** go to **Gait Speed Test** (page 2)
- Held for **10s**: Mark **1,** go to the next test

1.B Points: ☐ *1pt max*

1.C) Tandem Stand *(Heel of one foot in front of toes of the other)*

☐ **Failed or Not attempted**
↳ **Reason:(Choose 1)**
- ☐ Unable for any reason
- ☐ Participant declined
- ☐ CRA judged unsafe to perform

☐ **Successful**
↳ **Seconds held** (0-10.00 sec.)**:** ☐☐.☐☐

- **Less than 3s** OR **Failed/Not attempted**: Mark **0**
- Held for **3s** to less than **10s**: Mark **1**
- Held for **10s**: Mark **2**

1.C Points: ☐ *2pts max*

Please fill out Subtotal for the Balance Test, then go to Gait Speed Test on Next Page →

Balance Test Subtotal: ☐ *4pts max*

1					Form	Version	
Patient ID					**URCC 13059 - GAP 70+** Short Physical Performance Battery (SPPB)	Amd2	Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Gait Speed Test

2.A) Walk 1 (Measures the time required to walk 3 meters at a normal pace)

☐ **Failed or Not attempted**
↳ **Reason:(Choose 1)**
- ☐ Unable for any reason
- ☐ Participant declined
- ☐ CRA judged unsafe to perform

☐ **Successful**
↳ **Completion Time** (in seconds)**:** ☐☐.☐☐

- **If time equals 0s** OR **Failed/Not attempted**: Go to **Chair Stand Test** (page 3)
- If **successful**, fill in **Completion Time** and proceed to **2.B**

2.B) Walk 2 (Measures the time required to walk 3 meters at a normal pace)

☐ **Failed or Not attempted**
↳ **Reason:(Choose 1)**
- ☐ Unable for any reason
- ☐ Participant declined
- ☐ CRA judged unsafe to perform

☐ **Successful**
↳ **Completion Time** (in seconds)**:** ☐☐.☐☐

Aids used for either walk: ☐ None

☐ Cane ☐ Walker

☐ Other (Specify): _____

- **If time equals 0s** OR **Failed/Not attempted**: Go to **Chair Stand Test** (page 3)
- If **successful**, fill in **Completion Time** and proceed to **2.C**

2.C) Fastest Time of the two walks.

Points earned if time =

- ☐ 0.01 to 3.61 seconds (4 pts)
- ☐ 3.62 to 4.65 seconds (3 pts)
- ☐ 4.66 to 6.52 seconds (2 pts)
- ☐ ≥ 6.53 seconds (1 pt)
- ☐ Failed or not attempted (0 pts)

Fastest Time (of either walk)**:** ☐☐.☐☐

Gait Speed Test Subtotal: ☐ *4pts max*

Go to Chair Stand Test on Next Page →

1					Form	Version		
Patient ID					**URCC 13059 - GAP 70+** Short Physical Performance Battery (SPPB)	Amd2	Patient Initials	

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Chair Stand Test

3.A) Pre-Test (Participants fold their arms across their chest and try to stand up once from a chair without using their arms)

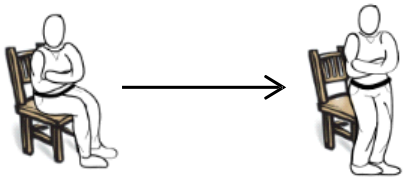
☐ **Failed or Not attempted**

↳ **Reason:(Choose 1)**

- ☐ Unable for any reason
- ☐ Participant declined
- ☐ CRA judged unsafe to perform

☐ **Successful**

↳ **Proceed to 3.B**



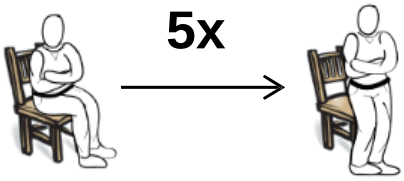
- **If Failed or Not attempted**: End Test
- If **successful**, proceed to **3.B**

3.B) 5 Repeats (Measures the time required to perform five rises from a chair to an upright position as fast as possible without the use of their arms) - Stop timer when patient stands upright 5th time

☐ **Failed or Not attempted**

↳ **Reason:(Choose 1)**

- ☐ Unable for any reason
- ☐ Participant declined
- ☐ CRA judged unsafe to perform



☐ **Successful**

↳ **Completion Time** (in seconds): ☐☐.☐☐

Points earned if time =

☐	0.01 to 11.19 seconds	(4 pts)
☐	11.20 to 13.69 seconds	(3 pts)
☐	13.70 to 16.69 seconds	(2 pts)
☐	16.70 to 60.00 seconds	(1 pt)
☐	≥ 60.01 seconds	(0 pts)
☐	0 seconds	(0 pts)

Subtotal Summation

Balance Test ☐ + **Gait Speed Test** ☐ + **Chair Stand Test** ☐ = ☐☐ **SPPB Total Sum** *(12 pts max)*

1 | | | | |

Patient ID

S | | | | |

Screening ID

Form	Version
URCC 13059 - GAP 70+ Geriatric Assessment Scoring Guide to Detect Impairments	Amd2

Patient Initials

● Screening

Completed by CRA			Impairment Cut-off Met?	
DOMAIN	**RESPONSES**	**SCORES Meeting the Cut-Off**	**No**	**Yes**
Polypharmacy	How many regularly scheduled medications does the patient take? 1 point for every regularly scheduled prescription medication listed on the Polypharmacy log (Response options: <5; ≥ 5)	≥ 5 points for regularly scheduled medications OR ≥ 1 point(s) for "yes" responses OR < 60 ml/min for CrCL or GFR (creatinine clearance on Labs form)	☐	☐
	How many "yes" responses on the High Risk Drug Review were there? 1 point for every 'Yes' response (Response options: 0, ≥ 1)			
	From the lab form, what was the patient's creatinine clearance? (Response options: < 60; ≥ 60 ml/min)			
BOMC	What was the patient's score on the BOMC? Response options: < 11, ≥ 11 points)	≥ 11 points	☐	☐
Mini Cog	How many words did the patient recall? (Response options: 0, 1, 2, 3 words)	0 words recalled OR 1-2 words recalled + abnormal clock	☐	☐
	Was the clock normal? (Response options: normal, abnormal)			
Weight Loss	What is the patient's percent of weight loss in the last 6 months? (Response options: ≤ 10%; > 10%)	> 10% weight loss in the past 6 months	☐	☐
BMI	What was the patient's BMI? (Response options: < 21.0; ≥ 21.0 kg/m2)	< 21.0 kg/m2	☐	☐
MNA	What was the patient's score on the MNA? (Response options: > 11, ≤11 points)	≤ 11 points	☐	☐
TUG	What was the patient's time on the TUG? (Response options: > 13.5, ≤13.5 sec)	> 13.5 seconds	☐	☐
SPPB	What was the patient's score on the SPPB? (Response options: ≤9; > 9 points)	≤ 9 points	☐	☐

1 | | | | |

Patient ID

S | | | | |

Screening ID

Form	Version
URCC 13059 - GAP 70+ Geriatric Assessment Scoring Guide to Detect Impairments	Amd2

Patient Initials

● Screening

DOMAIN	RESPONSES	SCORES Meeting the Cut-Off	Impairment Cut-off Met? No	Yes
	Completed by Patient			
ADL	In column A, how many "yes" responses were there? 1 point for every 'Yes' response (Response options: 0, ≥ 1)	≥ 1 point(s) for "yes" responses	☐	☐
Instrumental ADLs	How many "able to do with some help" or "completely unable to do" responses were there? 1 point for every "able to do with some help" or "completely unable to do" response (Response options: 0, ≥ 1)	≥ 1 point(s) for "able to do with some help" or "completely unable to do" responses	☐	☐
OARS Physical Health	How many "a lot" responses were there? 1 point for every "a lot" response (Response options: 0, ≥ 1)	≥ 1 point(s) for "a lot" responses	☐	☐
Falls History	On question 1, was the response "yes"? 1 point for 'Yes' response (Response options: 0, 1)	1 point for "yes" response on question #1	☐	☐
OARS Comorbidity	How many "yes" responses were there? 1 point for every 'Yes' response (Response options: 0, 1-2, ≥ 3) Including eyesight and hearing, how many "a great deal" responses were there? 1 point for every "a great deal" response (Response options: 0, ≥1)	≥ 3 points for "yes" responses OR ≥1 point(s) for "a great deal" responses (including eyesight and hearing)	☐	☐
GAD-7	What was the patient's score on the GAD-7? (Response options: <10 points, ≥10 points)	≥ 10 points	☐	☐
GDS	What was the patient's score on the GDS? (Response options: <5 points, ≥5 points)	≥ 5 points	☐	☐
OARS Medical Social Support	For **QUESTIONS 2-5**, how many "none," "a little," or "some of the time" responses were there? 1 point for every "none," "a little," or "some of the time" response (Response options: 0, ≥1)	≥ 1 point(s) for "none," "a little," or "some of the time" responses on QUESTIONS 2-5	☐	☐

1	Form	Version	
Patient ID	**URCC 13059 - GAP 70+** Cancer Treatment Status	Amd1	Patient Initials

● Baseline

Instructions: Complete this form if the cancer treatment plan is not initiated after the baseline visit. Please verify answers to questions with patient and oncologist.

1. Did the patient decide not to start cancer treatment?

- ☐ No, the decision was made solely by the oncologist (Skip to question 4)
- ☐ Yes, oncologist decided for them and they agreed
- ☐ Yes, decided together with oncologist
- ☐ Yes, decided on their own

2. Date decision made by the patient (mm/dd/yyyy): ☐☐ / ☐☐ / ☐☐☐☐

3. Reasons the patient is not starting cancer treatment. (check all that apply)

- ☐ Poor health status
- ☐ Does not want to deal with potential side effects of cancer treatment
- ☐ Feels the advantages of treatment do not outweigh the disadvantages
- ☐ Perceived effects on others
- ☐ Uncertainty of the resulting effect on their health
- ☐ Think that cancer treatment makes no sense as long as they feel well
- ☐ Due to seeing friends or family suffer from cancer treatment
- ☐ Financial reasons
- ☐ Other: ☐

4. Did the oncologist decide not to start cancer treatment? ☐ No ☐ Yes

4a. If Yes, why? (check all that apply)

- ☐ Patient has too many comorbid conditions
- ☐ Patient's cognitive status is very poor
- ☐ Patient's nutritional status is very poor
- ☐ Patient's support system is very poor (i.e. lacks a support system to adhere to treatment schedule, consistent access to reliable transportation)
- ☐ Patient's physical status is very poor
- ☐ Patient's functional status is very poor
- ☐ Patient's psychological status is very poor
- ☐ Patient's medication regimen is too complex and cannot be mitigated to allow for cancer treatment regimen
- ☐ Other: ☐☐☐☐☐☐☐☐☐☐

4b. Date decision made by oncologist (mm/dd/yyyy): ☐☐ / ☐☐ / ☐☐☐☐

Note: Patients for whom cancer treatment was not initiated will still be followed in the study.

1					Form	Version			
Patient ID					**URCC 13059 - GAP 70+** Cancer Treatment Status Follow-Up	Amd2			Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Instructions: Complete this form if the cancer treatment plan is stopped after the baseline visit. Also complete if treatment was held and not reinitiated. Please verify answers to questions with patient and oncologist.
Note: Please complete toxicity outcomes forms for 1 month after last treatment.

1. Did the patient decide to stop cancer treatment?

- ☐ No, the decision was made solely by the oncologist (Skip to question 4)
- ☐ Yes, oncologist decided for them and they agreed
- ☐ Yes, decided together with oncologist
- ☐ Yes, decided on their own

2. Date decision made by the patient (mm/dd/yyyy): ☐☐ / ☐☐ / ☐☐☐☐

3. Reasons the patient stopped cancer treatment. (check all that apply)

- ☐ Poor health status
- ☐ Does not want to deal with potential side effects of cancer treatment
- ☐ Feels the advantages of treatment do not outweigh the disadvantages
- ☐ Perceived effects on others
- ☐ Uncertainty of the resulting effect on their health
- ☐ Think that cancer treatment makes no sense as long as they feel well
- ☐ Due to seeing friends or family suffer from cancer treatment
- ☐ Financial reasons
- ☐ Cancer treatment break due to improved clinical outcome
- ☐ Other: ☐

4. Did the oncologist decide to stop cancer treatment? ☐ No ☐ Yes

4a. If Yes, why? (check all that apply)

- ☐ Patient has too many comorbid conditions
- ☐ Patient's cognitive status is very poor
- ☐ Patient's nutritional status is very poor
- ☐ Patient's support system is very poor (i.e. lacks a support system to adhere to treatment schedule, consistent access to reliable transportation)
- ☐ Patient's physical status is very poor
- ☐ Patient's functional status is very poor
- ☐ Patient's psychological status is very poor
- ☐ Patient's medication regimen is too complex and cannot be mitigated to allow for cancer treatment regimen
- ☐ Cancer treatment not effective
- ☐ Risks of cancer treatment outweigh the benefits
- ☐ Other: ☐

4b. Date decision made by oncologist (mm/dd/yyyy): ☐☐ / ☐☐ / ☐☐☐☐

Note: Patients for whom cancer treatment was discontinued will still be followed in the study.

URCC 13059

APPENDIX D:
Physician Measures

Physician REDCap Baseline Survey

1 What is your age (years old)? _____

2 What is your gender?
- ☐ Male
- ☐ Female

3 What is your ethnicity?
- ☐ Hispanic or Latino
- ☐ Non-Hispanic
- ☐ Unknown

4 What is your race? (Mark all that apply)
- ☐ White
- ☐ Black or African American
- ☐ American Indian of Alaskan Native
- ☐ Asian
- ☐ Native Hawaiian or Other Pacific Islander

5 How many years have you been in practice since finishing your oncology fellowship? _____

6 Are you board certified in oncology?
- ☐ Yes
- ☐ No

7 How many patients do you see in a typical work day? _____

8 How many days per week do you see patients?
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7

TRAINING AND EXPERIENCE

9. Please check the box that most accurately describes your feelings about the statement provided.

	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
9a. I believe that geriatrics training is essential for the care of older adults with cancer.	☐	☐	☐	☐	☐
9b. I frequently enlist the help of a social worker with specialized geriatrics training.	☐	☐	☐	☐	☐
9c. I frequently order home safety evaluations for my older patients	☐	☐	☐	☐	☐
9d. I would appreciate additional training in topics related to the care of older adults with cancer.	☐	☐	☐	☐	☐
9e. I believe that the medical care of older adults with cancer needs to be improved.	☐	☐	☐	☐	☐
9f. I use standardized geriatric assessment tools to help me make decisions about my patients.	☐	☐	☐	☐	☐
9g. I strive to reduce the number of medications that my older patients are taking.	☐	☐	☐	☐	☐
9h. I routinely ask my patients if they have a history of recent falls.	☐	☐	☐	☐	☐
9i. I believe there should be more clinical trials designed specifically for the elderly.	☐	☐	☐	☐	☐

CONFIDENCE IN GERIATRICS

Please Respond to the following items by selecting which most accurately describes your level of confidence performing the items below for older patients.

10. What is your level of confidence performing the following for older patients?

	Not At All Confident	Slightly Confident	Moderately Confident	Quite Confident	Very Confident
10a. Recognize, evaluate, and treat dementia	☐	☐	☐	☐	☐
10b. Recognize, evaluate, and treat urinary incontinence	☐	☐	☐	☐	☐
10c. Conduct and evaluate a functional assessment	☐	☐	☐	☐	☐
10d. Conduct an assessment of and an intervention for falls	☐	☐	☐	☐	☐
10e. Assess nutritional status	☐	☐	☐	☐	☐
10f. Make recommendations for rehabilitation	☐	☐	☐	☐	☐
10g. Recognize, evaluate, and treat depression	☐	☐	☐	☐	☐
10h. Recognize, evaluate, and treat delirium	☐	☐	☐	☐	☐
10i. Prevent and manage osteoporosis	☐	☐	☐	☐	☐
10j. Determine patient's social support/living experiences	☐	☐	☐	☐	☐
10k. Discuss advanced directives	☐	☐	☐	☐	☐

COMFORT WITH SHARED DECISION MAKING

Directions: The following statements ask you to share your thoughts about decision-making for cancer treatment. Please answer each question below by checking the box that best represents your opinion (check only one box per question).

11. Overall, how comfortable do you feel if a patient requests that:

	Not At All Comfortable	Slightly Comfortable	Moderately Comfortable	Quite Comfortable	Very Comfortable
11a. You make the decisions using all that is known about the treatments.	☐	☐	☐	☐	☐
11b. You make the decisions while strongly considering the patients' needs and priorities.	☐	☐	☐	☐	☐
11c. You and the patient make the decisions together on an equal basis.	☐	☐	☐	☐	☐
11d. The patient makes the decisions while strongly considering your opinion.	☐	☐	☐	☐	☐
11e. The patient makes the decisions using all they learn about the treatments.	☐	☐	☐	☐	☐
11f. The patient and caregiver should make treatment decisions with you.	☐	☐	☐	☐	☐
11g. The caregiver should make treatment decisions with you.	☐	☐	☐	☐	☐

ONCOLOGIST VIGNETTE

12 Vignette #1

AM is a 72 year old female with a history of well-controlled hypertension, hyperlipidemia and osteoarthritis, who is referred for evaluation of metastatic pancreatic cancer. She has a 3 cm pancreatic adenocarcinoma with metastatic disease to the liver. Based upon her cancer diagnosis, her estimated life expectancy is six months or less. She currently reports moderate fatigue which is impacting her daily activities (ECOG PS =1) but denies any other symptoms from her cancer. She independently performs all activities of daily living and instrumental activities of daily living. She denies any memory problems or history of dementia. She currently lives alone.

12 Vignette #2

BL is a 72 year old female with a history of well-controlled hypertension, hyperlipidemia and osteoarthritis, who is referred for evaluation of metastatic pancreatic cancer. She has a 3 cm pancreatic adenocarcinoma with metastatic disease to the liver. Based upon her cancer diagnosis, her estimated life expectancy is six months or less. She currently reports moderate fatigue which is impacting her daily activities (ECOG PS =1). She independently performs all activities of daily living but requires assistance with some instrumental activities of daily living including housekeeping and grocery shopping. She has had 3 falls in the past 6 months, and sustained an injury requiring an emergency room visit during one episode. She denies any other complaints. She denies any memory problems or history of dementia. She currently lives alone.

12 Vignette #3

CK is a 72 year old female with a history of well-controlled hypertension, hyperlipidemia and osteoarthritis, who is referred for evaluation of metastatic pancreatic cancer. She has a 3 cm pancreatic adenocarcinoma with metastatic disease to the liver. Based upon her cancer diagnosis, her estimated life expectancy is six months or less. She currently reports moderate fatigue, which is impacting her daily activities (ECOG PS =1). She independently performs all activities of daily living and most instrumental activities of daily living. She requires assistance with managing household finances due to memory problems. Cognitive testing is performed and her cognition is found to be impaired (MMSE 15)*. She denies any other complaints. She currently lives alone.

*A Mini-Mental State Exam Score (MMSE) of 15 is indicative of problems with learning new information, recognizing close relatives, personality changes, and behavior disorders.

12 Vignette #4

DJ is a 72 year old female with a history of well-controlled hypertension, hyperlipidemia and osteoarthritis, who is referred for evaluation of metastatic pancreatic cancer. She has a 3 cm pancreatic adenocarcinoma with metastatic disease to the liver. Based upon her cancer diagnosis, her estimated life expectancy is six months or less. She currently reports moderate fatigue, which is impacting her daily activities (ECOG PS =1). She independently performs all activities of daily living but requires assistance with some instrumental activities of daily living including housekeeping, grocery shopping, and managing finances. She has had 3 falls in the past 6 months, and sustained an injury requiring an emergency room visit during one episode. Cognitive testing is performed and her cognition is found to be impaired (MMSE 15)*. She denies any other complaints. She currently lives alone.

*A Mini-Mental State Exam Score (MMSE) of 15 is indicative of problems with learning new information, recognizing close relatives, personality changes, and behavior disorders.

12 Vignette #5

EK is an 84 year old female with a history of well-controlled hypertension, hyperlipidemia and osteoarthritis, who is referred for evaluation of metastatic pancreatic cancer. She has a 3 cm pancreatic adenocarcinoma with metastatic disease to the liver. Based upon her cancer diagnosis, her estimated life expectancy is six months or less. She currently reports moderate fatigue, which is impacting her daily activities (ECOG PS =1), but denies any other symptoms from her cancer. She independently performs all activities of daily living and instrumental activities of daily living. She denies any memory problems or history of dementia. She currently lives alone.

12 Vignette #6

FH is an 84 year old female with a history of well-controlled hypertension, hyperlipidemia and osteoarthritis, who is referred for evaluation of metastatic pancreatic cancer. She has a 3 cm pancreatic adenocarcinoma with metastatic disease to the liver. Based upon her cancer diagnosis, her estimated life expectancy is six months or less. She currently reports moderate fatigue, which is impacting her daily activities (ECOG PS =1). She independently performs all activities of daily living, but requires assistance with some instrumental activities of daily living including housekeeping and grocery shopping. She has had 3 falls in the past 6 months, and sustained an injury requiring an emergency room visit during one episode. She denies any other complaints. She denies any memory problems or history of dementia. She currently lives alone.

12 Vignette #7

GS is an 84 year old female with a history of well- controlled hypertension, hyperlipidemia and osteoarthritis, who is referred for evaluation of metastatic pancreatic cancer. She has a 3 cm pancreatic adenocarcinoma with metastatic disease to the liver. Based upon her cancer diagnosis, her estimated life expectancy is six months or less. She currently reports moderate fatigue, which is impacting her daily activities (ECOG PS =1). She independently performs all activities of daily living and most instrumental activities of daily living. She only requires assistance with managing household finances due to memory problems. Cognitive testing is performed and is found to be impaired (MMSE 15)*. She denies any other complaints. She currently lives alone.

*A Mini-Mental State Exam Score (MMSE) of 15 is indicative of problems with learning new information, recognizing close relatives, personality changes, and behavior disorders.

12 Vignette #8

HT is an 84 year old female with a history of well-controlled hypertension, hyperlipidemia and osteoarthritis, who is referred for evaluation of metastatic pancreatic cancer. She has a 3 cm pancreatic adenocarcinoma with metastatic disease to the liver. Based upon her cancer diagnosis, her estimated life expectancy is six months or less. She currently reports moderate fatigue, which is impacting her daily activities (ECOG PS =1). She independently performs activities of daily living but requires assistance with some instrumental activities of daily living including housekeeping, grocery shopping and managing finances. She has had 3 falls in the past 6 months, and sustained an injury requiring an emergency room visit during one episode. Cognitive testing is performed and her cognition is found to be impaired (MMSE 15)*. She denies any other complaints. She currently lives alone.

*A Mini-Mental State Exam Score (MMSE) of 15 is indicative of problems with learning new information, recognizing close relatives, personality changes, and behavior disorders.

12a. Based on the information provided, would you offer this patient treatment that includes chemotherapy?
- ☐ Yes
- ☐ No

12a. If Yes, what would you offer? _____

12b. What dosing would you prescribe?
- ☐ Full
- ☐ Reduced
- ☐ Other

12b.iIf other, please specify: _____

12c. What treatment schedule would you prescribe? _____

12d. What supportive care interventions would you recommend (if any)? _____

Physician ID

Form: **URCC 13059 - GAP 70+**
Physician Follow-up Survey (Usual Care)

Version: Amd2

Physician Initials

Please respond to the following items by checking the box that most appropriately describes your level of confidence performing the items below for older patients.

What is your level of confidence performing the following for your older patients?

	Not At All Confident	A Little Confident	Somewhat Confident	Confident	Very Confident
a. Recognize, evaluate, and treat dementia.	☐	☐	☐	☐	☐
b. Recognize, evaluate, and treat urinary incontinence.	☐	☐	☐	☐	☐
c. Conduct and evaluate a functional assessment.	☐	☐	☐	☐	☐
d. Assessment of and an intervention for falls.	☐	☐	☐	☐	☐
e. Assessing nutritional status.	☐	☐	☐	☐	☐
f. Making recommendations for geriatric rehabilitation.	☐	☐	☐	☐	☐
g. Recognize, evaluate, and treat depression.	☐	☐	☐	☐	☐
h. Recognize, evaluate, and treat delirium.	☐	☐	☐	☐	☐
i. Preventing and managing osteoporosis.	☐	☐	☐	☐	☐
j. Determination of your patient's social support/living experiences.	☐	☐	☐	☐	☐
k. Advanced directives discussion.	☐	☐	☐	☐	☐

Physician ID	Form	Version	Physician Initials
	URCC 13059 - GAP 70+ Physician Follow-up Survey (Intervention)	Amd2	

Please respond to the following items by checking the box that most appropriately describes <u>your level of confidence performing the items below for older patients</u>.

1. What is your level of confidence performing the following for your older patients?

	Not At All Confident	A Little Confident	Somewhat Confident	Confident	Very Confident
a. Recognize, evaluate, and treat <u>dementia</u>.	☐	☐	☐	☐	☐
b. Recognize, evaluate, and treat <u>urinary incontinence</u>.	☐	☐	☐	☐	☐
c. Conduct and evaluate a <u>functional assessment</u>.	☐	☐	☐	☐	☐
d. Assessment of and an intervention for <u>falls</u>.	☐	☐	☐	☐	☐
e. Assessing <u>nutritional status</u>.	☐	☐	☐	☐	☐
f. Making recommendations for <u>geriatric rehabilitation</u>.	☐	☐	☐	☐	☐
g. Recognize, evaluate, and treat <u>depression</u>.	☐	☐	☐	☐	☐
h. Recognize, evaluate, and treat <u>delirium</u>.	☐	☐	☐	☐	☐
i. Preventing and managing <u>osteoporosis</u>.	☐	☐	☐	☐	☐
j. Determination of your <u>patient's social support/living experiences</u>.	☐	☐	☐	☐	☐
k. <u>Advanced directives</u> discussion.	☐	☐	☐	☐	☐

2. The following questions ask you your opinion of the geriatric assessment (GA). Please indicate your level of agreement with the following statements.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a. The GA influenced my cancer treatment decisions.	☐	☐	☐	☐	☐
b. The GA helped increase my awareness of areas that would influence patient outcomes that I had not thought about previously.	☐	☐	☐	☐	☐
c. The GA was too long.	☐	☐	☐	☐	☐
d. The GA was comprehensive and covered the most important geriatric health concerns adequately.	☐	☐	☐	☐	☐
e. I would encourage my colleagues to use the GA for their patients who are ≥ 70 years old.	☐	☐	☐	☐	☐

3. What did you like best about the GA, if anything?

4. What would you change about the GA, if anything?

1					Form	Version		
Patient ID					**URCC 13059 - GAP 70+** Treatment Decision Making Form	Amd2		Patient Initials

Physician ID

● Baseline

1. What is the patient's cancer diagnosis?
Please mark an X in all that apply.

☐ Adrenal	☐ Larynx	☐ Ovarian
☐ Anal	☐ Leukemia	☐ Pancreatic
☐ Bladder	☐ Lip & Oral cavity	☐ Pharyngeal
☐ Bone (e.g., osteosarcoma)	☐ Liver	☐ Prostate
☐ Breast Cancer	☐ Lung	☐ Rectal
☐ Brain Tumor	☐ Lymphoma	☐ Salivary
☐ Carcinoid (GI)	☐ Melanoma	☐ Sarcoma (not osteosarcoma)
☐ Cervical	☐ Merkle Cell	☐ Testicular
☐ Colon	☐ Mesothelioma	☐ Thyroid
☐ Endometrial	☐ Multiple Myeloma	☐ Unkown Primary
☐ Esophageal	☐ Nasal & Sinus	☐ Uterine
☐ Gastric (Stomach)	☐ Neuroblastoma	☐ Vaginal/Vulvar
☐ Kidney	☐ Neuroendocrine	

☐ Other, Specify:

2. What is the patient's disease stage?
Please mark an X in the corresponding box and write as needed in the textbox provided.

☐ III

☐ IV

☐ Other, Specify:

3. Is the patient currently receiving or planning to receive any of the following treatments in the next 2 months?

Please mark an X in all corresponding boxes that apply and write as needed in the textbox provided.

Treatments	No	Yes	Unsure
a. Intravenous Chemotherapy	☐	☐	☐
b. Other Medical Therapies for Cancer			
b-1. Oral Chemo	☐	☐	☐
b-2. Vaccines	☐	☐	☐
b-3. Biologics	☐	☐	☐
b-4. Immunotherapies	☐	☐	☐
c. Hormonal Therapy	☐	☐	☐
d. Palliative Radiation Therapy	☐	☐	☐
e. Other Cancer Treatments, Specify:	☐	☐	☐
f. Other Cancer Treatments, Specify:	☐	☐	☐

4. Listed below are several variables that oncologists consider when determining treatment regimens for their patients.

Please indicate which variables you considered when developing this patient's treatment plan.

For the following variables mark an X to represent No/Yes in the corresponding box. For those variables you considered when developing your treatment plan, please rate them according to how they influenced your decision by placing an X in the corresponding box from a 1 rated as not important to a 10 rated as very important.

	No	Yes	If yes, please rate by order of importance	Not Important 1	2	3	4	5	6	7	8	9	Very Important 10
a. Age	☐	☐	If yes →	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
b. Performance Status	☐	☐	If yes →	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
c. Comorbid Conditions	☐	☐	If yes →	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
d. Patient Preference for Treatment Options	☐	☐	If yes →	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
e. Limited Life Expectancy from Comorbidities (non-malignancy)	☐	☐	If yes →	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
f. Potential Side Effects from Treatment	☐	☐	If yes →	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
g. Physical Limitations	☐	☐	If yes →	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
h. Nutritional Status	☐	☐	If yes →	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
i. Cognitive Status	☐	☐	If yes →	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
j. Social Support	☐	☐	If yes →	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
k. Psychological Status	☐	☐	If yes →	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

5. Did any other factors influence your decision to initiate the current treatment plan?
Please mark an X in the corresponding box and write your answer in the textbox provided.

☐ No ☐ Yes

8a. Please Describe:

6. Would the treatment plan be different for a patient 50 years of age or younger?
Please mark an X in the corresponding box and write your answer in the textbox provided.

☐ No ☐ Yes

1				

Patient ID

Physician ID

Form	Version
URCC 13059 - GAP 70+ Decision Regret Follow-up	Amd2

Patient Initials

○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

Please reflect on the decision you made about this patient's treatment plan.

Instructions: Please reflect on all the decisions you have had to make with the patient about the patient's care since all of this began. Please show how strongly you agree or disagree with these statements by marking an "**X**" in the check box that best fits your views about your decisions for the patient's cancer care.

Please mark an X in the corresponding box.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. I believe the right decisions have been made.	☐	☐	☐	☐	☐
2. I regret the choices that were made.	☐	☐	☐	☐	☐
3. I would make the same choices if I had to do it over again.	☐	☐	☐	☐	☐
4. The choice did the patient a lot of harm.	☐	☐	☐	☐	☐
5. The decisions were wise.	☐	☐	☐	☐	☐

Patient ID	Form	Version	Patient Initials
1	**URCC 13059 - GAP 70+** Understanding of Disease - Physician	Amd2	

Physician ID

● Baseline

Instructions: The following are questions about what you believe about the patient's illness. They ask about the patient's quality of life and how long you think the patient might live. Please mark an "**X**" in the check box that best corresponds to your answer for each question.

1. To the best of your knowledge, is the patient's cancer curable?

☐ Yes ☐ No ☐ Uncertain

2. What do you believe are the chances that the patient's cancer will go away and never come back with treatment?

☐ 100% ☐ More than 50% ☐ 50/50 ☐ Less than 50%

☐ 0% ☐ Uncertain

3. How much longer do you expect the cancer treatments to extend the patient's life expectancy?

☐ None ☐ Less than 1 month ☐ 1 to 3 months ☐ 4 to 6 months

☐ 7 to 12 months ☐ More than 1 year ☐ Decline to answer

4. How do you think cancer treatment will affect the patient's quality of life, if at all?

☐ Improve it a lot ☐ Improve it a little ☐ No Change ☐ Decrease it a little

☐ Decrease it a lot

5. Considering the patient's health, and underlying medical conditions, what would <u>you</u> estimate the patient's overall life expectancy to be?

☐ 0 to 6 months ☐ 7 to 12 months ☐ Between 1 to 2 years

☐ Between 2 to 5 years ☐ More than 5 years

6. Considering the patient's health, and underlying medical conditions, what do you think <u>the patient</u> estimates his or her overall life expectancy to be?

☐ 0 to 6 months ☐ 7 to 12 months ☐ Between 1 to 2 years

☐ Between 2 to 5 years ☐ More than 5 years

URCC 13059

APPENDIX E:
Study Related Forms

Screening Log **Date:** _____ **Site:** _____ **CRA:** _____

(Send to Research Base Biweekly)

										COACH ONLY			
Patient Approached #	GAP Study (Y/N)	COACH Study (Y/N)	Patient Screen #	Physian (last name, first initial)	Reason Ineligible	Reason Patient Declined When Approached	Patient Signed Consent (Y/N)	Estimated Screen Date	Estimated Enrollment Date	Caregiver (Y/N)	Reason Caregiver Declined When Approached	Caregiver Signed Consent (Y/N)	Comments
TOTAL	0	0	0	0	0	0	0	0	0	0	0	0	

List of Reasons for Ineligibility

1. Physician does not want to participate in the study
2. Patient is < 70 years of age
3. Cancer stage is 1 or 2 (not advanced)
4. Has surgery planned within 3 months of consent.
5. Patient or healthcare proxy does not understand the English language
6. Will not have oncology visits planned for 3 months +/or not willing to come in for study visits
7. Could not provide informed consent or did not have a healthcare proxy
8. Patient has already made a decision to forgo any cancer treatment (i.e., only being followed in best supportive care or hospice)
9. Other

GAP ONLY Reasons for Patient Inelibility

10. GAP ONLY: Doesn't have a plan to start a new chemotherapy regimen within 4 weeks of enrollment
11. GAP ONLY: Doesn't have a plan to be on chemotherapy for at least 3 months (minimum 70 days)
12. GAP ONLY: Has brain metastases at time of study consent process.

COACH ONLY Reasons for Caregiver Inelibility

13. COACH ONLY: Caregiver not 21 years or older.
14. COACH ONLY: Caregiver not able to understand consent due to cognitive, health or sensory impairment
15. COACH ONLY: Caregiver does not understand the English language

Note: *Patients who have previously received surgery or any cancer treatment are eligible. *COACH ONLY: Patients receiving any cancer treatment are eligible

*GAP ONLY: Patients who will receive monoclonal antibody therapy, other cancer therapies (e.g., tyrosine kinase inhibitors), or radiation therapy are eligible as long as this is in combination with chemotherapy

Reasons Subjects Declined When Approached for Study

1. Doesn't have the energy or feel well enough
2. Family/social issues
3. Too time consuming/burdensome
4. Does not want to complete surveys
5. Job/Employment issues
6. No reason given
7. In hospital/hospice
8. Other

COACH ONLY Reasons

9. COACH ONLY: Does not want to be audiorecorded
10. COACH Caregiver ONLY: Patient does not want caregiver to participate

1				

Patient ID

S				

Screening ID

Form	Version
URCC 13059 - GAP 70+ Patient Eligibility Checklist	Amd2

Patient Initials

● Screening

[FOR OFFICE USE ONLY - NOT SHARED WITH PATIENT]

Screening Date: ☐☐ / ☐☐ / ☐☐☐☐

INCLUSION CRITERIA (all answers must be YES to be eligible)

☐ Yes ☐ No **1.** Is 70 years of age or older.

☐ Yes ☐ No **2.** Has a diagnosis of advanced solid tumor malignancy (advanced cancer) or lymphoma. *Patients with stage III cancer or lymphoma are eligible if cure is not possible or anticipated. Clinical staging without pathological confirmation is allowed.*

☐ Yes ☐ No **3.** Plans to start a new cancer treatment regimen within 4 weeks from time of baseline registration.
(The treatment regimen must include a chemotherapy drug or other agents that have similar prevalence of toxicity. Patients who will receive monoclonal antibody therapy or other cancer therapies (e.g., tyrosine kinase inhibitors) are eligible if the other agents present a prevalence of toxicity similar to chemotherapy. These therapies can be used in combination with chemotherapy, as a single agent, or in combination with each other. A list of allowable agents meeting the toxicity criteria will be available on the URCC NCORP Research Base website as part of the study materials. If the potentially eligible subject is receiving a drug not on the list, contacting the URCC NCORP Research Base study team is required for approval prior to subject enrollment. Patients who are receiving approved cancer treatment in combination with radiation are eligible. A patient may also be enrolled on a treatment trial and participate in this study, if all other inclusion and exclusion criteria are met).

☐ Yes ☐ No **4.** Plans to be on chemotherapy or other allowable treatment for at least 3 months (minimum 70 days) and be willing to come in for study visits.

☐ Yes ☐ No **5.** Has at least 1 geriatric assessment domain impaired other than Polypharmacy per Table 1 in the protocol.

☐ Yes ☐ No **6.** Able to provide informed consent, or if the oncology physician determines the patient to not have decision-making capacity, a patient-designated health care proxy (or authorized representative per institutional policies) must sign consent by the baseline visit.

☐ Yes ☐ No **7.** Is able to read and understand English.

EXCLUSION CRITERIA (all answers must be NO to be eligible)

☐ Yes ☐ No **8.** Has surgery planned within 3 months of consent. Patients who have previously received surgery are eligible.

☐ Yes ☐ No **9.** Has brain metastases at time of study consent process.*(Patients with history of treated brain metastases are eligible if they are not symptomatic at the time of study enrollment.)*

Form completed by (printed):	
Form completed by (signature):	Date: __/__/____
Physician's Name:	
Physician's Signature:	Date: __/__/____

Patient ID	Form	Version	Patient Initials
1	**URCC 13059 - GAP 70+** Patient Status/Withdrawal	Amd2	
S (Screening ID)			

Instructions: Please review all options with respondent and mark all that apply

Screening Period:

Instructions: The screening period is defined as the period after consent and prior to baseline registration.

1. Screen Failure **Date:** ☐☐ / ☐☐ / ☐☐☐☐

- ☐ Ineligible; not meeting inclusion criteria at time of consent
- ☐ Patient too ill
- ☐ Ineligible; meeting exclusion criteria at time of consent
- ☐ Died after consent
- ☐ Other:

2. Screen Withdrawal **Date:** ☐☐ / ☐☐ / ☐☐☐☐

- ☐ Family/Social Issues
- ☐ Does not want to complete study procedures
- ☐ Job/Employment Issues
- ☐ Does not want to complete surveys
- ☐ Doesn't have the energy or feel well enough
- ☐ Other:

Enrolled Patients(After Baseline Registration):

NON-Withdrawal Categories for Enrolled Patients (After Baseline Registration)

Instructions: *This is a sick, often fragile population*, therefore patients can partially or completely discontinue their own participation in study activities (surveys, study assessments) at any time without actively (verbally) withdrawing from the study. These enrolled patients will be considered **active with missing data**. CRAs should obtain chart medical data, as it relates to subject and cancer treatment outcomes unless the patient states in writing they do not wish this data to be collected. *Continuation of chart data extraction even if a patient declines to fill out surveys is very important for study validity. These procedures do not require patient participation.*

3. ☐ **Active with Missing Data** **Date:** ☐☐ / ☐☐ / ☐☐☐☐

- ☐ No longer to come to study visits *(Medical data will still be collected)*
- ☐ Decline/unable to complete surveys and/or CRA measures *(Medical data will still be collected)*
- ☐ Switched Medical Providers
- ☐ Other:

4. ☐ **Lost to Follow-up** **Date:** ☐☐ / ☐☐ / ☐☐☐☐

5. ☐ **Hospice Entry** **Date:** ☐☐ / ☐☐ / ☐☐☐☐

Withdrawal Categories for Enrolled Patients *(After Baseline Registration)*

Withdrawal is an explicit verbal statement from enrolled patients for all study contacts, patient related study procedures and participation to stop. Only patients can withdraw themselves from the study. CRAs cannot decide to withdraw a patient, for example if the patient declines or is unable to complete surveys or CRA administered assessments. Medical chart extraction as it relates to subject and cancer treatment outcomes will continue unless the patient states in writing they do not wish this data to be collected.

6. Study Withdrawal

☐ Family/Social Issues ☐ Relocation

☐ Job/Employment Issues ☐ Switched Medical Providers

☐ Other:

7. ☐ **Withdrew consent to continue to extract medical chart data** ***(Provide written documentation)***

Date: ☐☐ / ☐☐ / ☐☐☐☐

8. ☐ **Withdrew from study participation as defined above** ***(Provide written documentation)***

Date: ☐☐ / ☐☐ / ☐☐☐☐

Physician ID	Form	Version	Physician Initials
	URCC 13059 - GAP 70+ Physician Withdrawal Form	Amd2	

○ Baseline ○ 4-6 Weeks ○ 3 Month Follow-up ○ 6 Month Follow-up

1. Date of Withdrawal: ☐☐ / ☐☐ / ☐☐☐☐

2. Reason for Withdrawal (mark all that apply):

- ☐ Physician on leave
- ☐ Relocation/Leaving Practice
- ☐ Too time consuming/burdensome
- ☐ Does not want to complete surveys
- ☐ Retiring
- ☐ No reason given
- ☐ No longer seeing patients with solid tumors
- ☐ Other

3. Comments:

1 | | | | |

Patient ID

S | | | | |

Screening ID

Form	Version
URCC 13059 - GAP Survival Follow-Up	Amd2

| | | |

Patient Initials

Instructions: Please complete after patient has expired. Research base will request survival information for up to one year after enrollment.

1. Patient Deceased: Date of Death: | | / | | / | | | | |

2. Cause of Death:

- ☐ Complications/ Diagnosis of Cancer
- ☐ Other

3. Place of Death:

- ☐ Home or Apartment (belonging to self, friend, relative or other care taker) On Hospice
- ☐ Home or Apartment (belonging to self, friend, relative or other care taker) NOT on Hospice
- ☐ Long-term Care Facility (other than inpatient hospice)
- ☐ Inpatient Hospice or Palliative Care Unit
- ☐ Hospice Facility / Home
- ☐ Nursing Home
- ☐ Emergency Room
- ☐ Hospital / Acute Care Hospital
- ☐ Other

4. Comments:

URCC CCOP RESEARCH BASE ADVERSE EVENT (AE) REPORT

COMPLETE PER PROTOCOL AND FAX FORM AND SUPPORTING DOCUMENTATION TO:

Jacque Lindke
Fax 585-461-5601

CCOP	**Affiliate/Component**	**Investigator's Name** *(Print)*	**Reporter's Name** *(Print)*

URCC Protocol #	**Participant Study ID**	**Participant Initials**	**Report Type** ☐**Initial** ☐**Follow-up** **Date report submitted to URCC** ___/___/_____ *mm dd yyyy*

Participant Information				
Date of Birth ___/___/_____ *mm dd yyyy*	**Gender** ☐Male ☐Female	**Weight** _____ ☐kg ☐lb	**Height** _____ ☐cm ☐in	**Race** ☐White ☐Black ☐Hispanic ☐Asian ☐Other *(specify):* _____

Adverse Event (AE)	**Start Date** *(mm/dd/yyyy)*	**Stop Date** *(mm/dd/yyyy)*	**Grade** *(2-5, using NCI CTC)*	
	___/___/_____	___/___/_____ ☐continues	☐2 ☐4 ☐3 ☐5	☐Expected ☐Unexpected

Describe Event *(include clinical signs/symptoms, diagnoses, course of event, actions taken and outcome)*	**Seriousness Criteria** *(check all that apply)*
	☐fatal event – date of death __/__/____ ☐required/prolonged hospitalization ☐persistent/significant disability ☐life threatening ☐other significant medical event *(describe to the left)*
	Attribution
	☐unrelated ☐unlikely related ☐possibly related ☐probably related ☐definitely related

Other relevant medical history

URCC 13059

APPENDIX F:

Approved Other Agents with Similar Prevalence of Toxicity to Chemotherapy

Appendix F: Approved other agents with similar prevalence of toxicity to chemotherapy.

This list is not comprehensive but provides examples of drugs and regimens that would be allowed base on eligibility criteria.

The eligibility criteria are listed in the protocol in Section 4.2.

-Patients who will receive monoclonal antibody therapy or other cancer therapies (e.g., tyrosine kinase inhibitors) are eligible if the other agents present a prevalence of toxicity similar to chemotherapy. These therapies can be used in combination with chemotherapy, as a single agent, or in combination with each other.

> * Chemotherapy will be defined as cytotoxic drugs; in addition, agents (e.g., monoclonal antibodies and targeted agents) that have a prevalence of grade 3-5 toxicity in older patients similar to chemotherapy (>50%) will be allowed. A list of allowable agents (single and in combination) meeting this toxicity criteria will be available on the URCC NCORP Research Base website as part of the study materials. Given the rapidly changing landscape of new drugs for cancer, the study team led by the PI will update the list accordingly after reviewing the toxicity profile of new therapies. **If the potentially eligible participant is to receive an approved drug or regimen not on the list, contacting the URCC NCORP Research Base study team is required for approval prior to participant enrollment**.

The below list is an example of drugs that would be approved based on safety data in phase III studies. Whenever possible, safety data for older patients are included.

REVIEWED AND APPROVED

DRUG OR REGIMEN	INDICATION	COMMENTS
Regorafenib	Colon cancer, Gastrointestinal stromal tumor	Over 50% of patients experienced grade 3-5 toxicity.[1] Close to 60% of patients required dose reductions due to toxicity.[1]
Sunitinib	Gastrointestinal stromal tumor Renal Cell Carcinoma Bone cancer	Significant toxicity (>50%) noted in studies of elderly with renal cell carcinoma. Significant (>50%) of patients require dose reductions.[2-4]
Sorafenib	Hepatocellular carcinoma Patients receiving sorafenib for renal cell carcinoma are not eligible due to decreased risk of toxicity in this population.	Fifty-one percent of older adults with hepatocellular carcinoma had severe toxicities and 40% had dose reductions.[5,6]
Bevacizumab and interferon in combination	Renal cell carcinoma	Grade 3-5 toxicity rate is 79%.[7]
Axitinib	Renal cell carcinoma	High rates of diarrhea, fatigue and hand-foot.[8] Limited data in elderly.
Imatinib at 800 mg dose	Any advanced solid tumor that this dose has indication for	Grade 3-5 toxicity rate is 63%.[9]
Palbociclib-fulvestrant and palbociclib-letrozole	Breast cancer	Grade 3-5 toxicity rate is >60%.[10]
Cabozantinib	Thyroid cancer	Grade 3-5 toxicity rate >60% and dose reductions in 70%.[11]
Ramucirumab monotherapy	Gastric/GE Junction cancer	Grade 3-5 toxicity rate is >58%.[12]
Enzalutamide	Prostate cancer	Grade 3-5 toxicity is 50% in older patients.[13,14]
Abiraterone	Prostate cancer	Grade 3-5 toxicity is 50-60% in older patients.[15,16]
Revlimid	Lymphoma	Grade 3-4 toxicity higher in older vs younger patients (>70%).[17]
Dabrafenib and Trametinib combination Dafrabenib as a single agent is not approved. Trametinib as a single agent is not approved.	Melanoma	Grade 3-5 toxicity is >52%.[18]
Vemurafenib	Melanoma	Grade 3-5 toxicity is >60%.[18]

REVIEWED AND NOT APPROVED

DRUG OR REGIMEN	INDICATION	COMMENTS
Cetuximab monotherapy	Colon cancer Head and neck cancer Lung cancer	Grade 3-5 toxicity rates are 20% or less.
Panitumumab monotherapy	Colon cancer	Grade 3-5 toxicity rates are 20% or less.
Bevacizumab monotherapy		Grade 3-5 toxicity rates are 20% or less.
Temsirolimus	Renal cell carcinoma	Grade 3-5 toxicity rates are 20% or less.
Pazopanib	Renal cell carcinoma sarcoma	Grade 3-5 toxicity rates are less than 50%.
Everolimus	Renal cell carcinoma Breast cancer	Grade 3-5 toxicity rates are less than 40%.
Lapatinib	Breast cancer	Grade 3-5 toxicity rates are 20% or less.
Trastuzumab emtansine	Breast cancer	Grade 3-5 toxicity rates are less than 50%.
Erlotinib	Lung cancer	Grade 3-5 toxicity rates are 20% or less.
Crizotinib	Lung cancer	Grade 3-5 toxicity rates are 20% or less.
Nivolumab	Lung cancer Melanoma	Grade 3-5 toxicity rates are 20% or less.
Obinutuzumab	Lymphoma	Grade 3-5 toxicity rates are 20% or less.
Bendamustine plus Rituxan	Lymphoma	Grade 3-5 toxicity rates are less than 50%.
Bendamustine	Lymphoma	Grade 3-5 toxicity rates are less than 50%.
Rituxan	Lymphoma	Grade 3-5 toxicity rates are less than 50%.
Alemtuzumab plus Rituxan	Lymphoma	Grade 3-5 toxicity rates are less than 50%.
Ibrutinib	SLL	Grade 3-5 toxicity rates are less than 50%.
Pembrolizumab	Melanoma	Grade 3-5 toxicity rates are less than 50%.
ipilimumab	Melanoma	Grade 3-5 toxicity rates are 20% or less.
Dafabrenib Monotherapy	Melanoma	Grade 3-5 toxicity rates are <50%.[19]
Trametinib Monotherapy	Melanoma	Grade 3-5 toxicity rates are <50%.[20]

1. Grothey A, Van Cutsem E, Sobrero A, et al. Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial. Lancet 2013;381:303-12.
2. Derbel Miled O, Dionne C, Terret C, et al. Sorafenib and sunitinib for elderly patients with renal cell carcinoma. Journal of geriatric oncology 2013;4:255-61.
3. Brunello A, Basso U, Sacco C, et al. Safety and activity of sunitinib in elderly patients (>/= 70 years) with metastatic renal cell carcinoma: a multicenter study. Annals of oncology : official journal of the European Society for Medical Oncology / ESMO 2013;24:336-42.
4. De Giorgi U, Scarpi E, Sacco C, et al. Standard vs adapted sunitinib regimen in elderly patients with metastatic renal cell cancer: results from a large retrospective analysis. Clinical genitourinary cancer 2014;12:182-9.
5. Edeline J, Crouzet L, Le Sourd S, et al. Sorafenib use in elderly patients with hepatocellular carcinoma: caution about use of platelet aggregation inhibitors. Cancer chemotherapy and pharmacology 2015;75:215-9.
6. Wong H, Tang YF, Yao TJ, et al. The outcomes and safety of single-agent sorafenib in the treatment of elderly patients with advanced hepatocellular carcinoma (HCC). The oncologist 2011;16:1721-8.
7. Rini BI, Halabi S, Rosenberg JE, et al. Phase III trial of bevacizumab plus interferon alfa versus interferon alfa monotherapy in patients with metastatic renal cell carcinoma: final results of CALGB 90206. Journal of clinical oncology : official journal of the American Society of Clinical Oncology 2010;28:2137-43.
8. Motzer RJ, Escudier B, Tomczak P, et al. Axitinib versus sorafenib as second-line treatment for advanced renal cell carcinoma: overall survival analysis and updated results from a randomised phase 3 trial. The Lancet Oncology 2013;14:552-62.
9. Blanke CD, Rankin C, Demetri GD, et al. Phase III randomized, intergroup trial assessing imatinib mesylate at two dose levels in patients with unresectable or metastatic gastrointestinal stromal tumors expressing the kit receptor tyrosine kinase: S0033. Journal of clinical oncology : official journal of the American Society of Clinical Oncology 2008;26:626-32.
10. Turner NC, Huang Bartlett C, Cristofanilli M. Palbociclib in Hormone-Receptor-Positive Advanced Breast Cancer. The New England journal of medicine 2015;373:1672-3.
11. Elisei R, Schlumberger MJ, Muller SP, et al. Cabozantinib in progressive medullary thyroid cancer. Journal of clinical oncology : official journal of the American Society of Clinical Oncology 2013;31:3639-46.
12. Fuchs CS, Tomasek J, Yong CJ, et al. Ramucirumab monotherapy for previously treated advanced gastric or gastro-oesophageal junction adenocarcinoma (REGARD): an international, randomised, multicentre, placebo-controlled, phase 3 trial. Lancet 2014;383:31-9.
13. Sternberg CN, de Bono JS, Chi KN, et al. Improved outcomes in elderly patients with metastatic castration-resistant prostate cancer treated with the androgen receptor inhibitor enzalutamide: results from the phase III AFFIRM trial. Annals of oncology : official journal of the European Society for Medical Oncology / ESMO 2014;25:429-34.
14. Graff JN, Baciarello G, Armstrong AJ, et al. Efficacy and safety of enzalutamide in patients 75 years or older with chemotherapy-naive metastatic castration-resistant prostate cancer: results from PREVAIL. Annals of oncology : official journal of the European Society for Medical Oncology / ESMO 2015.
15. Smith MR, Rathkopf DE, Mulders PF, et al. Efficacy and Safety of Abiraterone Acetate in Elderly (75 Years or Older) Chemotherapy Naive Patients with Metastatic Castration Resistant Prostate Cancer. The Journal of urology 2015;194:1277-84.
16. Mulders PF, Molina A, Marberger M, et al. Efficacy and safety of abiraterone acetate in an elderly patient subgroup (aged 75 and older) with metastatic castration-resistant prostate cancer after docetaxel-based chemotherapy. European urology 2014;65:875-83.

17. Revilimid package insert: http://wwwrevlimidremscom/pdf/REV_Full_Prescribing_Informationpdf.
18. Robert C, Karaszewska B, Schachter J, et al. Improved overall survival in melanoma with combined dabrafenib and trametinib. The New England journal of medicine 2015;372:30-9.
19. Long GV, Trefzer U, Davies MA, et al. Dabrafenib in patients with Val600Glu or Val600Lys BRAF-mutant melanoma metastatic to the brain (BREAK-MB): a multicentre, open-label, phase 2 trial. The Lancet Oncology 2012;13:1087-95.
20. Flaherty KT, Robert C, Hersey P, et al. Improved survival with MEK inhibition in BRAF-mutated melanoma. The New England journal of medicine 2012;367:107-14.