E2Z02 Case Report Forms Packet

SOAPP (Symptom Outcomes and Practice Patterns): A Survey of Disease and Treatment-Related Symptoms in Patients with Invasive Cancer of the Breast, Prostate, Lung or Colon/Rectum

ECOG Investigators: The following forms must be submitted to the ECOG Coordinating Center, FSTRF, 900 Commonwealth Avenue, Boston, MA 02215 (ATTN: DATA).

FORMS SUBMISSION SCHEDULE

NOTE: To ensure accurate and complete logging of forms at the ECOG Coordinating Center, forms should be submitted for each required time period, regardless of whether there is new data to report.

BASELINE
Within One Week After Registration: E2Z02 Baseline Data Form (#2430, 12/6/06) E2Z02 Clinician On-Study Form (#2431, 12/6/06) E2Z02 Patient On-Study Form (#2432, 12/6/06) E2Z02 Medication Form (#2433, 12/6/06) E2Z02 MDASI-ECOG Form (#2434, 12/6/06) E2Z02 Assessment Compliance Form (#2435, 12/6/06)
FOLLOW-UP
28-35 Days After Baseline: E2Z02 Clinician Follow-up Form (#2436, 12/6/06) E2Z02 Patient Follow-up Form (#2437, 12/6/06) E2Z02 Medication Form (#2433, 12/6/06) E2Z02 MDASI-ECOG Form (#2434, 12/6/06) E2Z02 Assessment Compliance Form (#2435, 12/6/06)

E2Z02 Forms Submission Schedule by Reporting Period

Reporting Periods While On Study

On Study Report Period	Baseline	Follow-Up[1]
Forms Required	Baseline Data Form	
	Clinician On-Study Form	Clinician Follow-Up Form
	Patient On-Study Form	Patient Follow-Up Form
	Medication Form	Medication Form
	MDASI-ECOG Form	MDASI-ECOG Form
	Assessment Compliance Form	Assessment Compliance Form

[1] Between 28-35 days from Baseline

Form No. 2430

E2Z02 Baseline Data Form

INSTRUCTIONS: Complete this form and submit original to the ECOG Coordinating Center within one week of registration. Keep a copy for your files.

PLACE ID LABEL HERE

Patient Initials (Last, First) ____
ECOG Protocol Number ____ ECOG Patient ID ____
Participating Group Protocol Number ____ Participating Group Patient ID ____
Institution/Affiliate ____

E 2 Z 0 2 **ECOG Protocol Number**

☐☐☐☐☐ **ECOG Patient ID**

BDF **DCI Name**

1 **Registration Step** **Report period:** X Baseline

☐ Please mark an 'X' if data have been amended
(Please circle amended items in red)

Date(s) Data Amended __/__/____ (M D Y)
__/__/____ (M D Y)

☐☐/☐☐/☐☐☐☐ Assessment Date (M D Y)

Disease Characteristics

Primary Site(s) (Place an 'X' in the appropriate boxes)

☐ Breast ☐ Prostate

☐ Colorectal ☐ Lung

☐☐/☐☐☐☐ Date of initial pathologic/clinical/radiographic diagnosis (M Y) ☐ (Mark an 'X' if unknown)

If patient has multiple primaries, please indicate additional sites

☐☐
☐☐
☐☐

01=Bone
02=Brain
04=Effusion/Ascites
05=GI (Other)
06=GU (Other)
07=Head & Neck
08=Liver
10=Nodes
11=Skin
14=Pleura
15=Leukemia
16=Lymphoma
99=Other, Specify____

Disease Status

Current Status of Disease

☐
1=CR (Complete Disappearance of Lesions)
2=PR (Partial Response)
3=SD (Stable)
4=PD (Progression)

Current Stage of Disease

☐
1=NED (No evidence of disease)
2=Local/regional
3=Metastatic
4=Local/regional and metastatic

☐☐/☐☐☐☐ Date of initial diagnosis of metastatic disease (if applicable) (M Y) ☐ (Mark an 'X' if not applicable)

Disease Status (cont.)

Metastatic Site(s): (Please mark an 'X' for all that apply)

☐ Abdominal/visceral ☐ Brain
☐ Breast ☐ Bone
☐ Bone marrow ☐ Leptomeningeal or epidural
☐ Liver ☐ Lung
☐ Pleuritic ☐ Soft tissue/nodes
☐ Other________________ ☐ Other visceral, specify____________

ECOG Performance Status (On date of this evaluation)

☐ 0=Fully active, able to carry on all pre-disease performance without restriction (Karnofsky 90-100)
1=Restricted in physically strenuous activity but ambulatory (K 70-80)
2=Ambulatory and capable of all selfcare but unable to carry out any work activities (K 50-60)
3=Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours (K 30-40)
4=Completely disabled (K 10-20)

Weight loss in previous six months

☐ 1= <5% of body weight
2=5 - <10% of body weight
3=10 - <20% of body weight
4= ≥20% of body weight

Prior Treatment For Cancer

Has the patient had prior chemotherapy/immunotherapy/hormonal therapy?

☐ 1=No
2=Yes

If yes:

Total number of prior chemotherapy/immunotherapy/hormonal therapy regimens

☐ 1=1 Regimen
2=2 Regimens
3=3 or more Regimens

Prior radiation therapy?

☐☐ 01=No
02=Yes
-1=Unknown

Current Treatment For Cancer

Is the patient currently receiving treatment for cancer?

☐ 1=No (Follow-up only)(Skip remainder of form)
2=Yes

If yes:

Type of therapy patient is currently receiving

☐ 1=Adjuvant
2=Neoadjuvant
4=Recurrent/Non-metastatic
5=Metastatic

Current Treatment For Cancer (cont.)

Current chemotherapy/immunotherapy/hormonal therapy
01=No, 02=Yes, -1=unknown

- [ ][ ] chemotherapy, single-agent cytotoxic systemic
- [ ][ ] chemotherapy, multi-agent cytotoxic systemic
- [ ][ ] chemotherapy, non-cytotoxic (e.g. endostatin, mmpi, TKI)
- [ ][ ] chemotherapy – not otherwise specified (includes non-systemic chemotherapy)
- [ ][ ] immunotherapy
- [ ][ ] hormonal therapy

Current radiation therapy?
[ ][ ] 01=No
02=Yes
-1=Unknown

Start Dates of Current Treatment

	M	D	Y
Chemotherapy	[ ][ ] /	[ ][ ] /	[ ][ ][ ][ ]
Immunotherapy	[ ][ ] /	[ ][ ] /	[ ][ ][ ][ ]
Hormonal therapy	[ ][ ] /	[ ][ ] /	[ ][ ][ ][ ]
Radiation therapy	[ ][ ] /	[ ][ ] /	[ ][ ][ ][ ]

Investigator Signature Investigator Signature Date

E2Z02 Clinician On-Study Form

INSTRUCTIONS: Complete this form at the time of the initial visit and submit original to the ECOG Coordinating Center within one week of registration. Keep a copy for your files.

E 2 Z 0 2 **ECOG Protocol Number**

☐☐☐☐☐ **ECOG Patient ID**

CLIN_ON_STUDY **DCI Name**

1 **Registration Step** **Report period:** X Baseline

PLACE ID LABEL HERE

Patient Initials (Last, First) ____________
ECOG Protocol Number ________ ECOG Patient ID ____________
Participating Group Protocol Number ____________ Participating Group Patient ID ____________
Institution/Affiliate ____________

☐ Please mark an 'X' if data have been amended
(Please circle amended items in red)

Date(s) Data Amended ___/___/___ (M D Y)
___/___/___ (M D Y)

☐☐/☐☐/☐☐☐☐ Assessment Date (M D Y)

Section 1

Specify which type of clinician is filling out form

☐ 1=Attending Physician
2=Resident or fellow
3=Advanced practice nurse or nurse practitioner
4=Physician assistant
5=Other, specify______________

Type of contact

☐ 1=No Contact
2=Face to Face
3=Telephone
4=E-mail
5=Web Portal
6=Other

Reason for contact

☐ 1=Routine, on-schedule
2=Off-schedule, unexpected
3=N/A, No Contact

Revised Edmonton Staging System (rESS)

The following items are part of a pain classification system called the Revised Edmonton Staging System (rESS) that is used with the permission of Dr. Robin Fainsinger.

For each of the following features, code the response that is most appropriate, based on your clinical assessment of the patient.

1. Mechanism of Pain

☐ 1=No pain syndrome
2=Any nociceptive combination of visceral and/or bone or soft tissue pain
3=Neuropathic pain syndrome with or without any combination of nociceptive pain
4=Insufficient information to classify

2. Incidental Pain

☐ 1=Absence of incidental pain
2=Presence of incidental pain
3=Insufficient information to classify

3. Psychological Distress and Addictive Behavior

☐ 1=Psychological distress and addictive behavior not present
2=Psychological distress alone present
3=Addictive behavior alone present
4=Psychological distress and addictive behavior present
5=Insufficient information to classify

4. Cognitive Function

☐ 1=No impairment. Patient able to provide accurate present and past pain history unimpaired
2=Partial impairment. Sufficient impairment to affect patient's ability to provide accurate present and/or past pain history
3=Total impairment. Patient unresponsive, delirious or demented to the stage of being unable to provide any present and past pain history
4=Insufficient information to classify.

Patient Initials: Last ____ , First ____ ECOG Patient ID ____________________________

Section 2

How long has the patient had some form of pain?

☐ 1=No current pain problem
2=Less than the past 48 hours
3=Less than the past 1 month
4=More than the past 1 month
5=More than the past 6 months

What treatments or medications are being provided for pain?

(Please code an answer of "01=No", "02=Yes" or "-1=Unknown" for each of the following treatments)

☐☐ Systemic Opioids

☐☐ Non-opioids

☐☐ Opioid/Non-opioid combination

☐☐ Surgery

☐☐ Neuroaxial opioids (epidural or intrathecal)

☐☐ Nerve block

☐☐ Other, specify____________

The patient has pain due to (Please mark an 'X' for all that apply):

☐ Primary disease (cancer)

☐ Effects of cancer treatment

☐ Medical condition unrelated to primary disease

☐ Psychological causes more than actual nociception

☐ Other, Specify_______________________________

Section 3

CONSULTATION: Is patient being referred to another physician or multi-disciplinary team for symptom management?

☐ 1= No
2= Yes

If yes, please code the service(s):

☐☐ ☐☐ ☐☐

01=Pain
02=Palliative Care
03=Combined Pain and Palliative Care
04=Psychiatry
05=Physical Therapy/Occupational Therapy
06=Nutrition
07=Chaplain
08=Wound/Enterostomal
09=Speech Therapy
10=Practitioner of Complementary Therapy (Yoga, massage, aromatherapy, etc.)
11=Other, Specify____________________
12=Radiation Therapy Service

Please indicate the top 3 areas **in order of importance** that are causing difficulties for this patient as far as you can tell.

☐☐ 1st

☐☐ 2nd

☐☐ 3rd

01=pain
02=fatigue
03=nausea
04=disturbed sleep
05=being distressed (upset)
06=dyspnea
07=cognitive difficulties
08=anorexia/cachexia
09=drowsiness
10=dry mouth
11=sad/depressed
12=vomiting
13=numbness/tingling
14=constipation
15=sore mouth
16=rash/pruritis
17=difficulty walking
18=lack of information
19=financial problems
20=family problems
21=existential worries
22=spiritual problems

Section 4

Overall, how much do you think this patient is bothered by difficulties related to comorbidities other than cancer (or the primary disease for which you are seeing the patient)?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

Overall, how much do you think this patient is bothered by difficulties related directly to cancer (or the primary disease for which you are seeing the patient)?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

Overall, how much do you think this patient is bothered by difficulties related to treatment of cancer (i.e. chemotherapy or other systemic therapy, radiation therapy, surgery)?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

Overall, how much do you think this patient is bothered by side effects from medications used to treat pain or other symptoms?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

Overall, how much do you think this patient is bothered by weight gain or loss?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

How would you rate this patient's overall quality of life at this time?

☐ 1=Very poor
2=Poor
3=Fair
4=Good
5=Excellent

Relative to other patients with same stage of disease, how would you categorize the degree of difficulty in caring for this patient's physical/psychological symptoms?

☐ 1=Very difficult
2=Difficult
3=Average
4=Easier than average
5=Much easier than average

Investigator Signature ____________ Investigator Signature Date ____________

Form No. 2432

E2Z02 Patient On-Study Form

INSTITUTION INSTRUCTIONS: Have the patient complete this form (in blue or black ink) at the intervals required per protocol and submit original to the ECOG Coordinating Center. Keep a copy for your files.

E	2	Z	0	2	**ECOG Protocol Number**
					ECOG Patient ID

PT_ON_STUDY **DCI Name**

1 **Registration Step** **Report period:** X Baseline

PLACE ID LABEL HERE

Patient Initials (Last, First) ____________________

ECOG Protocol Number ________ ECOG Patient ID ________

Participating Group Protocol Number ________ Participating Group Patient ID ________

Institution/Affiliate ____________________

PATIENT INSTRUCTIONS: The following questions will help the study team understand your health and the influence of symptoms on your quality of life. Please place a number in the box to represent your response to each question.

☐☐/☐☐/☐☐☐☐ Assessment Date
M D Y

1. What is your current employment status?
   ☐ 1=Working, Full-Time
   2=Working, Part-Time
   3=Not in the workforce (e.g., retired, disabled, student, homemaker)

2. Has your employment status changed due to illness?
   ☐ 1=No
   2=Yes

3. In general, would you say your overall quality of life is:
   ☐ 1=Excellent
   2=Good
   3=Fair
   4=Poor
   5=Very Poor

4. Have you driven a car within the past 4 weeks?
   ☐ 1=No
   2=Yes

5. Have you participated in a support group within the past 4 weeks?
   ☐ 1=No
   2=Yes

6. Have you received individual counseling within the past 4 weeks?
   ☐ 1=No
   2=Yes

7. Is there any history of depression in yourself:
   ☐ 1=No
   2=Yes

8. Is there any history of depression in your mother or father:
   ☐ 1=No
   2=Yes

9. Is there any history of depression in your brother(s) or sister(s):
   ☐ 1=No
   2=Yes

(continued):

10. Overall, how much are you bothered by difficulties related to health problems other than cancer?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

11. Overall, how much are you bothered by difficulties related directly to cancer?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

12. Overall, how much are you bothered by difficulties related to the treatment of cancer (i.e. chemotherapy or other systemic therapy, radiation therapy, surgery)?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

13. Overall, how much are you bothered by side effects from medications used to treat pain or other symptoms?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

14. Did anyone come with you to this office visit?

☐ 1=No
2=Yes

15. Overall, how much are you bothered by weight gain or loss?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

E2Z02 Medication Form

INSTRUCTIONS: Complete and submit this form at baseline, and at follow-up. Please indicate what medications the patient is taking according to the list below. Submit forms to the ECOG Coordinating Center. Keep a copy for your files.

E 2 Z 0 2 **ECOG Protocol Number**

ECOG Patient ID

CON_MED **DCI Name**

1 **Registration Step**

PLACE ID LABEL HERE

Patient Initials (First, Last)________

ECOG Protocol Number ________ ECOG Patient ID ________

Participating Group Protocol Number ________ Participating Group Patient ID ________

Institution/Affiliate ________

Please mark an 'X' if data have been amended (Please circle amended items in red)

Date(s) Data Amended __/__/____ (M D Y)
__/__/____ (M D Y)

Report Period
Choose one (☒) :

☐ Baseline ☐ Follow-Up (28-35 days)

Is patient currently taking medications (this reporting period)?
01=No (Skip rest of form)
02=Yes
-1=Unknown (no contact with patient)

Section 1 - Pain Medications

Agent Code (Consult list of agents below)	**Action Taken with this Agent (this reporting period)** 1=Initiated at this visit 2=Discontinued at this visit 3=Continuing at this visit	**This medication was prescribed by:** 1=Medical-oncology professional 2=Other oncology professional 3=Other physician/non-oncology	**Usual Dose per day (mg)** (For opioids only)

LONG ACTING OPIOID TREATMENT
01=Long acting morphine
02=Oxycontin
03=Transdermal Fentanyl
04=Methadone
05=Intrathecal pump

IMMEDIATE RELIEF/BREAKTHROUGH OPIOID TREATMENT
06=Morphine
07=Oxycodone
08=Hydromorphone
09=Oral Transmucosal fentanyl
10=Hydrocodone/acetaminophen
11=Codeine/acetaminophen
12=Propoxyphene/acetaminophen
13=SQ or IV opioids

OTHER TREATMENTS FOR PAIN
14=Common NSAID
15=COX-2 inhibitor
17=Acetaminophen
18=Muscle relaxant
19=Herbal or other supplements
20=Acupuncture referral
21=Nerve block referral
32=Corticosteroids
87=Anticonvulsant treatment for nerve pain
89=Antidepressant treatment for nerve pain
91=Topical therapy for pain control

Patient's Initials F____ , L____ ECOG Patient ID ____________________

Section 2 - Other Medications

Agent Code (Consult list of agents below)	Action Taken with this Agent (this reporting period) 1=Initiated at this visit 2=Discontinued at this visit 3=Continuing at this visit	This medication was prescribed by: 1=Medical-oncology professional 2=Other oncology professional 3=Other physician/non-oncology
☐☐	☐	☐
☐☐	☐	☐
☐☐	☐	☐
☐☐	☐	☐
☐☐	☐	☐
* ☐☐ ________________	☐	☐
* ☐☐ ________________	☐	☐
* ☐☐ ________________	☐	☐

*For an agent not listed, please code 88 for other and list the agent on the line

ANTIBACTERIAL ANTIBIOTICS
22=Prophylactic antibiotics
23=Treatment of current infection

ANTIFUNGAL AGENTS
24=Prevention of thrush
25=Treatment of current thrush
26=Treatment of systemic fungal infection

ANTIEMETICS
27=5HT3 antagonist
28=NK-1 antagonist (aprepitant, Emend)
29=Metoclopramide
30=Phenothiazines
31=Cannabinoids
32=Corticosteroids

BOWEL REGIMEN
33=Daily bowel regimen to prevent constipation
34=Stool softeners regularly
35=Senna-containing laxative regularly
36=Lactulose or sorbitol as needed

GASTRIC PROPHYLAXIS
37=Antacids
38=H2 blocker
39=Proton-pump inhibitor

GLYCEMIC CONTROL AGENTS
40=Sulfonylurea
41=Metformin
42=Long-acting insulin
43=Short-acting insulin

ANTIDEPRESSANT USE
44=Serotonin-Reuptake Inhibitor/newer anti-depressant
45=Tricyclic antidepressants
46=Psychostimulants

ANXIOLYTIC/SEDATIVE HYPNOTIC USE
47=Long acting agents (alprazolam, clonazepam, diazepam)
48=Intermediate-acting agents (temazepam, clorazepate)
49=Short-acting agents (lorazepam, midazolam)
50=Non-benzodiazepine (zolipedem, chloral hydrate)

ANTICOAGULANTS
51=Heparin (not including catheter flushes)
52=Low molecular weight heparin
53=Warfarin/Coumadin
54=Aspirin

ANTIHYPERTENSIVES
55=B-Blocker
56=Diurectic
57=Calcium-channel blocker
58=Angiotensin II inhibitor
59=ACE inhibitor

BONE PROTECTION AGENTS
60=Bisphosphonates
61=Calcium supplement
62=Vitamin D supplement
63=Angiotensin II inhibitor

VISCERAL ORGAN PROTECTION AGENTS
64=Amifostine
65=Dexrazoxane
66=Oxygen
67=IV Fluids

TREATMENT OF HOT FLASHES
68=Hormonal Agents
69=Antidepressant
70=Vitamin E

OTHER SYMPTOM AGENTS OR SUPPLEMENTS
71=Enteral nutrition supplement
72=Parenteral nutrition
73=Supplemental vitamins
74=Herbal supplements
75=Pilocarpine for dry mouth
76=Oral hygiene regimen
77=Glutamine or Gelclair
78=Progestational agents for appetite
79=Anabolic steroid for appetite

COLONY STIMULATING FACTORS
80=Erythropoietic agents
81=Thrombopoietic agent
82=G-CSF or GM-CSF
83=Topical ointment for skin rash
84=Oral medication for skin rash
85=Both topical ointment and oral medication for skin rash
86=Keratinocyte CSF (Palifermin)

How many different medications is the patient currently taking?

☐ 1=0-4
2=5-9
3=10 or more

____
Investigator Signature Investigator Signature Date

Patient Follow-Up Form Instructions

Do not submit this page to the ECOG Coordinating Center

Attached are the follow-up forms you agreed to fill out 28-35 days after the first set of forms were completed.

Please fill out these 2 forms any time between ___/___/______ and ___/___/______ (28-35 days after the first set of forms were completed).

We will call you at some time before day 35 to confirm that the forms were completed/mailed or to answer any questions.

Please be sure to place the completed forms in the self-addressed stamped envelope provided.

E2Z02 MDASI-ECOG Form

INSTITUTION INSTRUCTIONS: Have the patient complete this form (in blue or black ink) at the intervals required per protocol and submit original to the ECOG Coordinating Center. Keep a copy for your files.

| E | 2 | Z | 0 | 2 | **ECOG Protocol Number**

| | | | | | **ECOG Patient ID**

| MDASI | **DCI Name**

| 1 | **Registration Step**

PLACE ID LABEL HERE

Patient Initials (Last, First) ____________________
ECOG Protocol Number ________ ECOG Patient ID ____________
Participating Group Protocol Number ____________ Participating Group Patient ID ____________
Institution/Affiliate ____________________

Report Period Choose one (☒) : ☐ **Baseline** ☐ **Follow-up** **Assessment Date** __ __ / __ __ / __ __ __ __ (M / D / Y)

Part I. How **severe** are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been ***in the last 24 hours.*** Please fill in the circle below from 0 (symptom has not been present) to 10 (the symptom was as bad as you can imagine it could be) for each item.

	Not Present 0	1	2	3	4	5	6	7	8	9	As Bad As You Can Imagine 10
1. Your **pain** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
2. Your **fatigue (tiredness)** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
3. Your **nausea** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
4. Your **disturbed sleep** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
5. Your feelings of being **distressed (upset)** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
6. Your **shortness of breath** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
7. Your problem with **remembering** things at its WORST?	○	○	○	○	○	○	○	○	○	○	○
8. Your problem with **lack of appetite** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
9. Your feeling **drowsy (sleepy)** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
10. Your having a **dry mouth** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
11. Your feeling **sad** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
12. Your **vomiting** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
13. Your **numbness or tingling** at its WORST?	○	○	○	○	○	○	○	○	○	○	○

	Not Present 0	1	2	3	4	5	6	7	8	9	As Bad As You Can Imagine 10
14. Your **diarrhea (loose stools)** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
15. Your **constipation** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
16. Your **mouth sores** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
17. Your **skin rash** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
18. Your **hair loss** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
19. Your **coughing** at its WORST?	○	○	○	○	○	○	○	○	○	○	○

Part II. How have your symptoms interfered with your life?

Symptoms frequently interfere with how we feel and function. How much have your symptoms interfered with the following items ***in the last 24 hours***:

	Did Not Interfere 0	1	2	3	4	5	6	7	8	9	Interfered Completely 10
20. **General activity?**	○	○	○	○	○	○	○	○	○	○	○
21. **Mood?**	○	○	○	○	○	○	○	○	○	○	○
22. **Work** (including work around the house)?	○	○	○	○	○	○	○	○	○	○	○
23. **Relations** with other people?	○	○	○	○	○	○	○	○	○	○	○
24. **Walking?**	○	○	○	○	○	○	○	○	○	○	○
25. **Enjoyment of life?**	○	○	○	○	○	○	○	○	○	○	○

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Thank You

Do not submit this page to the ECOG Coordinating Center

Thank you for your participation in E2Z02, "A Survey of Disease and Treatment-Related Symptoms in Patients with Invasive Cancer: Prevalence, Severity, and Treatment".

Thank you for agreeing to complete the follow-up forms 28-35 days following the first set of forms.

We appreciate your honest answers and trust that they will help us better understand symptoms experienced by cancer patients.

Form No. 2435

E2Z02 Assessment Compliance Form

INSTRUCTIONS: Please complete this form according to the forms submission schedule. Submit original to the ECOG Coordinating Center. Keep a copy for your files.

| E | 2 | Z | 0 | 2 | **ECOG Protocol Number**

| | | | | | **ECOG Patient ID**

| ASMT_COMP | **DCI Name**

| 1 | **Registration Step**

PLACE ID LABEL HERE

Patient Initials (Last, First)________________

ECOG Protocol Number ______ ECOG Patient ID ______

Participating Group Protocol Number ______ Participating Group Patient ID ______

Institution/Affiliate ________________

Report Period (since start of treatment)
Choose one (☒) :

☐ Baseline ☐ Follow-Up (28-35 days)

(If not done at specified time points, choose intended time point.)

☐ Please mark an 'X' if data have been amended
(Please circle amended items in red)

Date(s) Data Amended __/__/____ (M D Y)
__/__/____ (M D Y)

Section I

__/__/____ (M D Y) Assessment Date
If not completed, enter date scheduled per E2Z02 protocol.

Section II - Assessments Not Completed

Were all of the quality of life forms completed for this timepoint?
☐ 1=no - Fill out each box of the corresponding column, for each form not completed
2=yes - Skip this section

	Patient On-Study Form (Only applicable at Baseline)	Patient Follow-Up Form (Only applicable at Follow-Up)	MDASI-ECOG
Assessment Form No.	2432	2437	2434
	1=no 2=yes	1=no 2=yes	1=no 2=yes
Indicate primary reason(s) why form was not completed:			
Patient refusal	☐	☐	☐
Unable to accommodate disability or language needs	☐	☐	☐
Specify disability or language: ______			
Patient did not show up in clinic/office	☐	☐	☐
Specify reason patient did not show up: ______			
Staff unavailable	☐	☐	☐
Patient not given form by staff	☐	☐	☐
Patient too ill	☐	☐	☐
Patient expired	☐	☐	☐
Assessment not required per protocol	☐	☐	☐
Specify reason assessment not required: ______			
Staff thought patient too ill	☐	☐	☐
Other	☐	☐	☐
Specify other reason: ______			

E2Z02 Assessment Compliance Form

Patient Initials: Last ____, First ____ ECOG Patient ID ____________________

Section III - Assessments Completed

Fill out the corresponding column for **each** quality of life form that was completed for this time point. Leave a column **blank** if the quality of life form was **not completed**.

	Patient On-Study Form (Only applicable at Baseline) 1=no 2=yes	Patient Follow-Up Form (Only applicable at Follow-Up) 1=no 2=yes	MDASI-ECOG 1=no 2=yes
Was Assessment self-administered?	☐	☐	☐

1=no - Complete each box in the corresponding column
2=yes - Skip remaining questions in this section for this form

How was the patient assisted?	1=no 2=yes	1=no 2=yes	1=no 2=yes
Were the questions read aloud to patient?	☐	☐	☐
Did the patient require clarification of questions or instructions?	☐	☐	☐
Did the patient require other assistance?	☐	☐	☐
Were the forms completed independently by another person?	☐	☐	☐

What was the reason for assistance?	1=no 2=yes	1=no 2=yes	1=no 2=yes
Did the patient have a language difficulty? (questions needed to be translated)	☐	☐	☐
Specify language: ____________________			
Did the patient have a literacy difficulty? (patient could not read well enough)	☐	☐	☐
Was the patient disabled?	☐	☐	☐
Specify disability: ____________________			
Were the forms completed via a telephone interview?	☐	☐	☐
Other	☐	☐	☐
Specify other reason: ____________________			

Who assisted or completed the Assessment?	1=no 2=yes	1=no 2=yes	1=no 2=yes
Staff	☐	☐	☐
Family	☐	☐	☐
Friend	☐	☐	☐
Other	☐	☐	☐
Specify other person: ____________________			

Investigator Signature ____________________ Investigator Signature Date ____________________

Form No. 2436

E2Z02 Clinician Follow-Up Form

INSTRUCTIONS: Please complete this form according to the forms submission schedule. Submit original to the ECOG Coordinating Center. Keep a copy for your files.

E	2	Z	0	2

ECOG Protocol Number

ECOG Patient ID

CLIN_FU **DCI Name**

1 **Registration Step** **Report period:** X Follow-Up (28-35 Days)

PLACE ID LABEL HERE

Patient Initials (Last, First) ______

ECOG Protocol Number ______ ECOG Patient ID ______

Participating Group Protocol Number ______ Participating Group Patient ID ______

Institution/Affiliate ______

Please mark an 'X' if data have been amended
(Please circle amended items in red)

Date(s) Data Amended ___/___/___ (M D Y)

___/___/___ (M D Y)

___/___/___ (M D Y) Assessment Date

Section 1

Specify which type of clinician is filling out form
- 1=Attending Physician
- 2=Resident or fellow
- 3=Advanced practice nurse or nurse practitioner
- 4=Physician assistant
- 5=Other, specify______

Type of contact
- 1=No Contact (Skip rest of form)
- 2=Face to Face
- 3=Telephone
- 4=E-Mail
- 5=Web Portal
- 6=Other

Reason for contact
- 1=Routine, on-schedule
- 2=Off-schedule, unexpected
- 3=N/A, No Contact

Is this clinician the same as at baseline?
- 1=No
- 2=Yes

Disease Status
- 1=Unchanged from prior visit
- 2=New evidence of response (good news)
- 3=New evidence of progression (bad news)

Current treatment for cancer (Include description and start date of treatment)
- 1=Unchanged
- 2=Changed

______

______

______

ECOG Performance Status (On date of this evaluation)
- 0=Fully active, able to carry on all pre-disease performance without restriction (Karnofsky 90-100)
- 1=Restricted in physically strenuous activity but ambulatory (K 70-80)
- 2=Ambulatory and capable of all selfcare but unable to carry out any work activities (K 50-60)
- 3=Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours (K 30-40)
- 4=Completely disabled (K 10-20)

Revised Edmonton Staging System (rESS)

The following items are part of a pain classification system called the revised Edmonton Staging System (rESS) that is used with the permission of Dr. Robin Fainsinger.

For each of the following features, code the response that is most appropriate, based on your clinical assessment of the patient.

1. Mechanism of Pain
   - 1=No pain syndrome
   - 2=Any nociceptive combination of visceral and/or bone or soft tissue pain
   - 3=Neuropathic pain syndrome with or without any combination of nociceptive pain
   - 4=Insufficient information to classify

Patient Initials: Last ____ , First ____ ECOG Patient ID ____________________________

Revised Edmonton Staging System (rESS) (cont.)

2. Incidental Pain

☐ 1=Absence of incidental pain
2=Presence of incidental pain
3=Insufficient information to classify

3. Psychological Distress and Addictive Behavior

☐ 1=Psychological distress and addictive behavior not present
2=Psychological distress alone present
3=Addictive behavior alone present
4=Psychological distress and addictive behavior present
5=Insufficient information to classify

4. Cognitive Function

☐ 1=No impairment. Patient able to provide accurate present and past pain history unimpaired
2=Partial impairment. Sufficient impairment to affect patient's ability to provide accurate present and/or past pain history
3=Total impairment. Patient unresponsive, delirious or demented to the stage of being unable to provide any present and past pain history
4=Insufficient information to classify.

Section 2

How long has the patient had some form of pain?

☐ 1=No current pain problem (Skip to Section 3)
2=Less than the past 48 hours
3=Less than the past 1 month
4=More than the past 1 month
5=More than the past 6 months

The patient has pain due to (Please mark an 'X' for all that apply):

☐ Primary disease (cancer)

☐ Effects of cancer treatment

☐ Medical condition unrelated to primary disease

☐ Psychological causes more than actual nociception

☐ Other, Specify________________________________

Section 3

Please indicate in **order of importance** the top 3 areas that are causing difficulties for this patient as far as you can tell.

☐☐ 1st

☐☐ 2nd

☐☐ 3rd

01=pain	12=vomiting
02=fatigue	13=numbness/tingling
03=nausea	14=constipation
04=disturbed sleep	15=sore mouth
05=being distressed (upset)	16=rash/pruritis
06=dyspnea	17=difficulty walking
07=cognitive difficulties	18=lack of information
08=anorexia/cachexia	19=financial problems
09=drowsiness	20=family problems
10=dry mouth	21=existential worries
11=sad/depressed	22=spiritual problems

Section 3 (cont.)

Overall, how much do you think this patient is bothered by difficulties related to comorbidities other than cancer (or the primary disease for which you are seeing the patient)?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

Overall, how much do you think this patient is bothered by difficulties related directly to cancer (or the primary disease for which you are seeing the patient)?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

Overall, how much do you think this patient is bothered by difficulties related to the cancer treatment (i.e. chemotherapy or other systemic therapy, radiation therapy, surgery)?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

Overall, how much do you think this patient is bothered by side effects from medications being used to treat pain or other symptoms?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

How would you rate this patient's overall quality of life at this time?

☐ 1=Very poor
2=Poor
3=Fair
4=Good
5=Excellent

Compared to this patient's previous visit, would you say his/her overall quality of life is?

☐ 1=Much better
2=Better
3=Nearly the same
4=Worse
5=Much worse

Relative to other patients with progressive/recurrent cancer, how would you categorize the degree of difficulty in caring for this patient's physical/psychological symptoms?

☐ 1=Very difficult
2=Difficult
3=Average
4=Easier than average
5=Much easier than average

Response to Symptom-Directed Treatment

☐ 1=Progressive symptoms
2=Stable symptoms
3=Partial improvement
4=Complete improvement

Patient Compliance with Symptom Treatment Recommendation

☐ 1=Perfect
2=Acceptable
3=Poor/Needs improvement

______________________ ______________________
Investigator Signature Investigator Signature Date

Patient Follow-Up Form Instructions

Do not submit this page to the ECOG Coordinating Center

Attached are the follow-up forms you agreed to fill out 28-35 days after the first set of forms were completed.

Please fill out these 2 forms any time between ___/___/______ and ___/___/______ (28-35 days after the first set of forms were completed).

We will call you at some time before day 35 to confirm that the forms were completed/mailed or to answer any questions.

Please be sure to place the completed forms in the self-addressed stamped envelope provided.

E2Z02 Patient Follow-Up Form

INSTITUTION INSTRUCTIONS: Have the patient complete this form (in blue or black ink) at the intervals required per protocol and submit original to the ECOG Coordinating Center. Keep a copy for your files.

E	2	Z	0	2	**ECOG Protocol Number**

☐☐☐☐☐ **ECOG Patient ID**

PT_FU **DCI Name**

1 **Registration Step** **Report period:** X Follow-Up (28-35 Days)

PLACE ID LABEL HERE

Patient Initials (Last, First) ______________

ECOG Protocol Number _______ ECOG Patient ID ___________

Participating Group Protocol Number ___________ Participating Group Patient ID ___________

Institution/Affiliate ______________

PATIENT INSTRUCTIONS: The following questions will help the study team understand your health and the influence of symptoms on your quality of life. Please place a number in the box to represent your response to each question.

☐☐/☐☐/☐☐☐☐ Assessment Date
M D Y

1. Compared to your previous visit, would you say your overall quality of life is:

☐ 1=Much better
2=Better
3=Nearly the same
4=Worse
5=Much worse

2. Do you currently drive a car?

☐ 1=No
2=Yes

3. Do you participate in a support group?

☐ 1=No
2=Yes

4. Do you receive individual counseling?

☐ 1=No
2=Yes

5. Overall, how much are you bothered by difficulties related to health problems other than cancer?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

6. Overall, how much are you bothered by <u>difficulties related directly to cancer?</u>

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

7. Overall, how much are you bothered by <u>difficulties related to the treatment of cancer</u> (i.e. chemotherapy or other systemic therapy, radiation therapy, surgery)?

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

8. Overall, how much are you bothered by <u>side effects from medications being used to treat pain or other symptoms?</u>

☐ 0=Not at all
1=A little bit
2=Moderately
3=Quite a bit
4=Extremely

Thank You

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Thank you for your participation in E2Z02, "A Survey of Disease and Treatment-Related Symptoms in Patients with Invasive Cancer: Prevalence, Severity, and Treatment".

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We appreciate your honest answers and trust that they will help us better understand symptoms experienced by cancer patients.

E2Z02 Forms Completion Guidelines

Do not submit this page

E2Z02 Baseline Data Form

This form is intended to assess the patient's disease characteristics and any prior treatment the patient may have received for his or her disease.

E2Z02 Clinician On-Study Form

This form is intended to assess the patient's overall symptoms from the point of view of the clinician during the first visit. It is not expected clinicians/physicians can precisely gauge subjective complaints of patients. Please do not feel threatened by this form. We are not profiling your quality of care.

E2Z02 Patient On-Study Form

This form is intended to assess the patient's overall symptoms from the point of view of the patient during the first visit.

E2Z02 Medication Form

This form is intended to assess the patient's prescribed medication, how often it is taken, if it is continuing, who prescribed it and what the intention of the medication was/is.

E2Z02 Clinician Follow-up Form

This form is intended to assess the patient's overall symptoms from the point of view of the clinician at the follow-up period. It is not expected clinicians/physicians can precisely gauge subjective complaints of patients. Please do not feel threatened by this form. We are not profiling your quality of care.

E2Z02 Patient Follow-up Form

This form is intended to assess the patient's overall symptoms from the point of view of the patient at the follow-up period.

E2Z02 Medication Form - Revised

INSTRUCTIONS: Complete and submit this form at baseline, and at follow-up. Please indicate what medications the patient is taking according to the list below. Submit forms to the ECOG Coordinating Center. Keep a copy for your files.

| E | 2 | Z | 0 | 2 | ECOG Protocol Number

| | | | | | ECOG Patient ID

CON_MED DCI Name

1 Registration Step

PLACE ID LABEL HERE

Patient Initials (Last, First) ______

ECOG Protocol Number ______ ECOG Patient ID ______

Participating Group Protocol Number ______ Participating Group Patient ID ______

Institution/Affiliate ______

___ Please mark an 'X' if data have been amended (Please circle amended items in red)

Date(s) Data Amended ___/___/___ (M D Y) ___/___/___ (M D Y)

Report Period

Choose one (☒) :

☐ Baseline ☐ Follow-Up (28-35 days)

__/__/____ (M D Y) Assessment Date

Is patient currently taking medications (this reporting period)?

☐☐ 01=No (Skip rest of form)
02=Yes
-1=Unknown (no contact with patient)

Section 1 - Pain Medications

Agent Code (Consult list of agents below)	Action Taken with this Agent (this reporting period) 1=Initiated at this visit 2=Discontinued at this visit 3=Continuing at this visit	This medication was prescribed by: 1=Medical-oncology professional 2=Other oncology professional 3=Other physician/non-oncology	Usual Dose per day (mg) (For opioids only)
☐☐	☐	☐	☐☐☐
☐☐	☐	☐	☐☐☐
☐☐	☐	☐	☐☐☐
☐☐	☐	☐	☐☐☐
☐☐	☐	☐	☐☐☐
☐☐	☐	☐	☐☐☐
☐☐	☐	☐	☐☐☐
☐☐	☐	☐	☐☐☐

LONG ACTING OPIOID TREATMENT
01=Long acting morphine
02=Oxycontin
03=Transdermal Fentanyl
04=Methadone
05=Intrathecal pump

IMMEDIATE RELIEF/BREAKTHROUGH OPIOID TREATMENT
06=Morphine
07=Oxycodone
08=Hydromorphone
09=Oral Transmucosal fentanyl
10=Hydrocodone/acetaminophen
11=Codeine/acetaminophen
12=Propoxyphene/acetaminophen
13=SQ or IV opioids

OTHER TREATMENTS FOR PAIN
14=Common NSAID
15=COX-2 inhibitor
17=Acetaminophen
18=Muscle relaxant
19=Herbal or other supplements
20=Acupuncture referral
21=Nerve block referral
32=Corticosteroids
87=Anticonvulsant treatment for nerve pain
89=Antidepressant treatment for nerve pain
91=Topical therapy for pain control

Patient's Initials L____ , F____ ECOG Patient ID ____________________

Section 2 - Other Medications

Agent Code (Consult list of agents below)	Action Taken with this Agent (this reporting period) 1=Initiated at this visit 2=Discontinued at this visit 3=Continuing at this visit	This medication was prescribed by: 1=Medical-oncology professional 2=Other oncology professional 3=Other physician/non-oncology
☐☐	☐	☐
☐☐	☐	☐
☐☐	☐	☐
☐☐	☐	☐
☐☐	☐	☐
* ☐☐ ________________	☐	☐
* ☐☐ ________________	☐	☐
* ☐☐ ________________	☐	☐

*For an agent not listed, please code 88 for other and list the agent on the line

ANTIBACTERIAL ANTIBIOTICS
22=Prophylactic antibiotics
23=Treatment of current infection

ANTIFUNGAL AGENTS
24=Prevention of thrush
25=Treatment of current thrush
26=Treatment of systemic fungal infection

ANTIEMETICS
27=5HT3 antagonist
28=NK-1 antagonist (aprepitant, Emend)
29=Metoclopramide
30=Phenothiazines
31=Cannabinoids
32=Corticosteroids

BOWEL REGIMEN
33=Daily bowel regimen to prevent constipation
34=Stool softeners regularly
35=Senna-containing laxative regularly
36=Lactulose or sorbitol as needed

GASTRIC PROPHYLAXIS
37=Antacids
38=H2 blocker
39=Proton-pump inhibitor

GLYCEMIC CONTROL AGENTS
40=Sulfonylurea
41=Metformin
42=Long-acting insulin
43=Short-acting insulin

ANTIDEPRESSANT USE
44=Serotonin-Reuptake Inhibitor/newer anti-depressant
45=Tricyclic antidepressants
46=Psychostimulants

ANXIOLYTIC/SEDATIVE HYPNOTIC USE
47=Long acting agents (alprazolam, clonazepam, diazepam)
48=Intermediate-acting agents (temazepam, clorazepate)
49=Short-acting agents (lorazepam, midazolam)
50=Non-benzodiazepine (zolipedem, chloral hydrate)

ANTICOAGULANTS
51=Heparin (not including catheter flushes)
52=Low molecular weight heparin
53=Warfarin/Coumadin
54=Aspirin

ANTIHYPERTENSIVES
55=B-Blocker
56=Diurectic
57=Calcium-channel blocker
58=Angiotensin II inhibitor
59=ACE inhibitor

BONE PROTECTION AGENTS
60=Bisphosphonates
61=Calcium supplement
62=Vitamin D supplement
63=Angiotensin II inhibitor

VISCERAL ORGAN PROTECTION AGENTS
64=Amifostine
65=Dexrazoxane
66=Oxygen
67=IV Fluids

TREATMENT OF HOT FLASHES
68=Hormonal Agents
69=Antidepressant
70=Vitamin E

OTHER SYMPTOM AGENTS OR SUPPLEMENTS
71=Enteral nutrition supplement
72=Parenteral nutrition
73=Supplemental vitamins
74=Herbal supplements
75=Pilocarpine for dry mouth
76=Oral hygiene regimen
77=Glutamine or Gelclair
78=Progestational agents for appetite
79=Anabolic steroid for appetite

COLONY STIMULATING FACTORS
80=Erythropoietic agents
81=Thrombopoietic agent
82=G-CSF or GM-CSF
83=Topical ointment for skin rash
84=Oral medication for skin rash
85=Both topical ointment and oral medication for skin rash
86=Keratinocyte CSF (Palifermin)

How many different medications is the patient currently taking?

☐ 1=0-4
2=5-9
3=10 or more

____
Investigator Signature Investigator Signature Date