

SCREENING : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit	/	/
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SCREENING : ENROLLMENT - Form Version: 03-May-2013 02:32

Site: Subject: Subject No:

Millennium C21005

1.	Randomization Number	
2.	Randomization Date	/ /
3.	Worst Pain Score at Screening	0 to 4 5 to 10
4.	Study Drug Scheduled Dose Level	mg
5.	Please select whether the patient is taking Prednisone or Prednisolone	
6.	Prednisone/Prednisolone Scheduled Dose Level	
7.	Enrollment under Protocol Version	

SCREENING : INCLUSION / EXCLUSION CRITERIA - Form Version: 17-Sep-2011 05:23

Site: Subject: Subject No:

Millennium C21005

1.	Does the patient satisfy all inclusion and exclusion criteria?	Yes No, please describe below.
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INCLUSION/EXCLUSION DEVIATION ENTRY

2.	Sequence Number	
	Criterion Number (Example: "E01")	
	Specify the Deviation (Example:"The patient was not of age, age = 17")	
	Was an exemption obtained from sponsor?	Yes No

SCREENING : DEMOGRAPHICS - Form Version: 03-May-2013 02:31

Site: Subject: Subject No:

Millennium C21005

1.	Patient Initials	
2.	Full Patient Number	
3.	Sex	Male
4.	Date of Birth	/ /
5.	Age	
6.	Ethnicity	Hispanic or Latino Not Hispanic or Latino Not Reported
7.	Race	White Black or African American Native Hawaiian or Other Pacific Islander Asian Asian Indian Chinese Japanese Korean Other (specify) Not Reported American Indian or Alaskan Native Other (specify) Not Reported

SCREENING : DEMOGRAPHICS - Form Version: 03-May-2013 02:31

Site: Subject: Subject No:
Millennium C21005

Start of Participation

8.	Date of Informed Consent	/	/
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Site: Subject: Subject No:

Millennium C21005

MEDICAL AND SURGICAL HISTORY

1.	Has the patient had any significant medical conditions or surgical procedures prior to enrollment?	Yes. Please enter details by clicking Add Entry below. No
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PLEASE RECORD:

- (1.) All significant lifetime medical history and
- (2.) All medical and surgical events from the last 5 years.
- (3.) Do NOT record diagnosis of Prostate or any treatments and procedures related to the disease under study.
- (4.) Record abnormalities reported during the Screening physical examination which meet the definitions of a medical history event.

2.	Sequence Number	
	Medical and Surgical History	Other, specify:
	Month/Year of Onset if known	/
	Status: Resolved or Ongoing?	Resolved Ongoing

Site: Subject: Subject No:

Millennium C21005

1.	Date of Initial Diagnosis	/ /
2.	Histological Classification	Known Other, Specify: Unknown

AT INITIAL DIAGNOSIS

3.	Primary Tumor	Known Unknown
4.	Regional Lymph Node	Known Unknown
5.	Distant Metastasis	Known Unknown
6.	Gleason Score	Primary Grade Secondary Grade Score Unknown

Site: Subject: Subject No:

Millennium C21005

AT STUDY ENTRY

7.	Stage at Study Entry	Other, specify Unknown
8.	How many documented bone lesions does the patient have?	
9.	Date of most recently confirmed disease progression by PSA	PSA Progression / / Not Applicable
10.	Date of most recently confirmed disease progression by radiographic disease	Radiographic Progression / / Not Applicable

SCREENING : PRIOR EVENTS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1.	Has the patient received prior antineoplastic therapy (systemic and localized, such as chemotherapy, immunotherapy, biological therapy, corticosteroids, etc.) related to the cancer under study?	Yes No
2.	Has the patient received prior radiation therapy related to the cancer under study?	Yes No
3.	Has the patient had any prior surgical procedures related to the cancer under study?	Yes No

SCREENING : PRIOR RADIATION - Form Version: 07-Oct-2010 00:09

Site: Subject: Subject No:

Millennium C21005

1.	Sequence Number	
2.	Anatomical Site	
3.	Start Date	/ /
4.	Stop Date	/ /
5.	Total Dose <i>(Format: xxxx.xx)</i>	Value Unit (cGy) centigrays (Gy) grays (RADS) rads Unknown
6.	Best Response	Complete Response (CR) Partial Response (PR) Stable Disease (SD) Progressive Disease (PD) Unable to Assess (UA) Unknown Symptom Relief

Site: Subject: Subject No:

Millennium C21005

Instructions: Record only surgeries related to the disease under study (excluding diagnostic biopsies).

1.	Sequence Number	
2.	Type of Surgical Procedure	Bilateral orchiectomy Cryotherapy Pelvic lymph node dissection Pelvic lymphadenectomy Radical prostatectomy Transurethral resection of the prostate (TURP) Other, specify:
3.	Date of Surgical Procedure	/ /

1.	Sequence Number	
2.	Regimen	Other, Specify
3.	Start Date (mmm/yyyy)	/
4.	Stop Date (mmm/yyyy)	/
5.	Best Response by RECIST	Complete Response (CR) Partial Response (PR) Stable Disease (SD) Progressive Disease (PD) Unable to Assess (UA) Unknown Not Applicable
6.	Date of Progression of Disease by RECIST	/ Not Applicable
7.	Date of Progression of Disease by PSA	/ Not Applicable
8.	Best Reponse by PSA	<= 0.2 ng/mL 90% Response 50% Response Stable Disease (SD) Progressive Disease (PD) Not Applicable

Site: Subject: Subject No:

Millennium C21005

9.	Bone Response	Progressive Disease Not Applicable
10.	Date of Progression of Disease in Bone	/ Not Applicable

Prior Therapy Other Agent Entry

11.	Sequence Number	
	Agent	
	Brand Name	
	Drug Record Number	
	Drug Sequence Number - 1	
	Drug Sequence Number - 2	
	Generic Name	
	Generic Record Number	
	Generic Sequence Number - 1	

Prior Therapy Other Agent Entry (Cont.)

11. (Cont.)	Generic Sequence Number - 2		
	Anatomical Therapeutic Classification		
	Anatomical Therapeutic Description		
	WHODRUG Version - Date		
	Coding Status		
	Coding Date	/	/
	Re-Code Flag		
	Clear coding	Clear coding	

SCREENING : VITAL SIGNS - Form Version: 03-May-2013 02:31

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Height <i>(Format: xxx.x)</i>	cm in Not Done
3.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
4.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
5.	Heart Rate	bpm Not Done
6.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

SCREENING : ECOG PERFORMANCE STATUS - Form Version: 07-Oct-2010 00:02

Site: Subject: Subject No:

Millennium C21005

1.	Score:	Done / Assessment / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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SCREENING : ECHO - Form Version: 07-Oct-2010 00:01

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Left Ventricular Ejection Fraction	Result % Not Reported
3.	Indicate ECHO Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Unevaluable

SCREENING : MUGA - Form Version: 07-Oct-2010 00:05

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Ejection Fraction	Result % Not Reported
3.	Indicate MUGA Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Not Evaluable

SCREENING : ELECTROCARDIOGRAM - Form Version: 03-May-2013 02:32

Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of ECG	/ / : Not Done
2.	Ventricular Rate	bpm Not Done
3.	PR <i>(Format: xxxxx)</i>	msec Not Done
4.	QRS <i>(Format: xxxxx)</i>	msec Not Done
5.	QT uncorrected <i>(Format: xxxxx)</i>	msec Not Done
6.	QTc Bazett	Done msec Not Done
7.	QTc Frederica	Done msec Not Done

SCREENING : ELECTROCARDIOGRAM - Form Version: 03-May-2013 02:32

Site: Subject: Subject No:

Millennium C21005

8. Indicate Interpretation of ECG results	Within Normal Limits Abnormal-Not clinically significant Abnormal-Clinically significant
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SCREENING : BRIEF PAIN INVENTORY SHORT FORM - Form Version: 17-Sep-2011 05:23

Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3. On the diagram, shade in the areas where you feel pain.

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Site: Subject: Subject No:

Millennium C21005

4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Site: Subject: Subject No:

Millennium C21005

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

SCREENING : SAMPLE COLLECTION - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:

Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled Hematology sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
4.	Was the scheduled PSA sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
5.	Was the scheduled Testosterone/DHEA-S sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

SCREENING : SAMPLE COLLECTION - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:

Millennium C21005

6.	Was the scheduled ACTH, Cortisol, Corticosterone sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
7.	Was the scheduled Lipid Profile, HbA1c sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
8.	Was the scheduled CTC Enumeration sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Site: Subject: Subject No:

Millennium C21005

MAGNETIC RESONANCE IMAGING (MRI)

1.	Date of MRI	/	/
Not Done			

COMPUTED TOMOGRAPHY (CT)

2.	Date of CT Scan	/	/
Not Done			

BONE SCAN

3.	Date of Bone Scan	/	/
Not Done			

Cycle 1 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit

/ /

Cycle 1 : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

1.	Did the patient receive any Study Drug during this cycle?	Yes No
2.	Did the patient receive any Prednisone during this cycle?	Yes: Was there any action taken on drug during this cycle? No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:

3. Did the patient receive any Prednisolone during this cycle?	Yes: Was there any action taken on drug during this cycle?	Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle: No
4. Was the scheduled dose level for any study drug modified during this cycle?	Yes No	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 1 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 1 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24
Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Score:	Done / Assessment / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3. On the diagram, shade in the areas where you feel pain.

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4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

Cycle 1 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /
	No

Cycle 1 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 1 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all	2:A little	3:Quite a bit	4:Very much
12.	Have you felt weak?	1:Not at all	2:A little	3:Quite a bit	4:Very much
13.	Have you lacked appetite?	1:Not at all	2:A little	3:Quite a bit	4:Very much
14.	Have you felt nauseated?	1:Not at all	2:A little	3:Quite a bit	4:Very much
15.	Have you vomited?	1:Not at all	2:A little	3:Quite a bit	4:Very much
16.	Have you been constipated?	1:Not at all	2:A little	3:Quite a bit	4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all	2:A little	3:Quite a bit	4:Very much
18.	Were you tired?	1:Not at all	2:A little	3:Quite a bit	4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all	2:A little	3:Quite a bit	4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 1 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30. How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

6. On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today.

Cycle 1 : PHARMACOKINETICS - Form Version: 07-Oct-2010 00:07

Site: Subject: Subject No:

Millennium C21005

1. PK Sample Collection Date and Time	Collection Date / /
	Sample Time :
	Not Done

Site: Subject: Subject No:

Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled Hematology sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
4.	Was the scheduled PSA sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
5.	Was the scheduled Testosterone/DHEA-S sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Site: Subject: Subject No:

Millennium C21005

6.	Was the scheduled ACTH, Cortisol, Corticosterone sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
7.	Was the scheduled CTC Enumeration sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
8.	Was the scheduled Whole Blood sample for Germline DNA obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Tumor Tissue

9.	What type of tumor tissue was provided?	Banked None
10.	Date Sample Taken:	/ /

Tumor Tissue (Cont.)

11.	Tissue Site of Sample:	Bone Brain Breast Effusion/Ascites GI GU Head and neck Liver Lung Nodes Skin Other, Specify
12.	By what method was sample obtained?	Core Needle Biopsy Incisional Biopsy Excisional Biopsy Other

Cycle 1 : SAMPLE COLLECTION - Form Version: 07-Oct-2010 00:01

Site: Subject: Subject No:

Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled CTC Biomarker sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Cycle 1 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 2 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit

/ /

Cycle 2 : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

1.	Did the patient receive any Study Drug during this cycle?	Yes No
2.	Did the patient receive any Prednisone during this cycle?	Yes: Was there any action taken on drug during this cycle? No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:

3. Did the patient receive any Prednisolone during this cycle?	Yes: Was there any action taken on drug during this cycle? No	Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:
4. Was the scheduled dose level for any study drug modified during this cycle?	Yes No	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 2 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 2 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Cycle 2 : ECOG PERFORMANCE STATUS - Form Version: 07-Oct-2010 00:02

Site: Subject: Subject No:

Millennium C21005

1. Score:	Done Assessment / / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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Cycle 2 : ELECTROCARDIOGRAM - Form Version: 03-May-2013 02:32

Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of ECG	/ / : Not Done
2.	Ventricular Rate	bpm Not Done
3.	PR <i>(Format: xxxxx)</i>	msec Not Done
4.	QRS <i>(Format: xxxxx)</i>	msec Not Done
5.	QT uncorrected <i>(Format: xxxxx)</i>	msec Not Done
6.	QTc Bazett	Done msec Not Done
7.	QTc Frederica	Done msec Not Done

Cycle 2 : ELECTROCARDIOGRAM - Form Version: 03-May-2013 02:32

Site: Subject: Subject No:

Millennium C21005

8. Indicate Interpretation of ECG results	Within Normal Limits Abnormal-Not clinically significant Abnormal-Clinically significant
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Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3.	On the diagram, shade in the areas where you feel pain.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50
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51
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4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

Cycle 2 : PHARMACOKINETICS - Form Version: 07-Oct-2010 00:07

Site: Subject: Subject No:

Millennium C21005

1. PK Sample Collection Date and Time	Collection Date / /
	Sample Time :
	Not Done

Cycle 2 : PHARMACOKINETICS - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:

Millennium C21005

1.	Cycle 2 Day 1 Draw 2: PK Sample Collection 2 Hours Post-Draw 1	Sample Time : Not Done
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Site: Subject: Subject No:

Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled Hematology sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
4.	Was the scheduled Testosterone/DHEA-S sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
5.	Was the scheduled ACTH, Cortisol, Corticosterone sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Cycle 2 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 3 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit

/ /

Cycle 3 : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

1.	Did the patient receive any Study Drug during this cycle?	Yes No
2.	Did the patient receive any Prednisone during this cycle?	Yes: Was there any action taken on drug during this cycle? No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:

3. Did the patient receive any Prednisolone during this cycle?	Yes: Was there any action taken on drug during this cycle? No	Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:
4. Was the scheduled dose level for any study drug modified during this cycle?	Yes No	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 3 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 3 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1. Score:	Done Assessment / / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3. On the diagram, shade in the areas where you feel pain.

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4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

Cycle 3 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /	
	No	

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 3 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all	2:A little	3:Quite a bit	4:Very much
12.	Have you felt weak?	1:Not at all	2:A little	3:Quite a bit	4:Very much
13.	Have you lacked appetite?	1:Not at all	2:A little	3:Quite a bit	4:Very much
14.	Have you felt nauseated?	1:Not at all	2:A little	3:Quite a bit	4:Very much
15.	Have you vomited?	1:Not at all	2:A little	3:Quite a bit	4:Very much
16.	Have you been constipated?	1:Not at all	2:A little	3:Quite a bit	4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all	2:A little	3:Quite a bit	4:Very much
18.	Were you tired?	1:Not at all	2:A little	3:Quite a bit	4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all	2:A little	3:Quite a bit	4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 3 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29.	How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30.	How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

- | | |
|--|--|
| 6. On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today. | |
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Site: Subject: Subject No:

Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled CTC Enumeration sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Cycle 3 : IMAGING ASSESSMENT - Form Version: 07-Oct-2010 00:00

Site: Subject: Subject No:

Millennium C21005

MAGNETIC RESONANCE IMAGING (MRI)

1.	Date of MRI	/	/
Not Done			

COMPUTED TOMOGRAPHY (CT)

2.	Date of CT Scan	/	/
Not Done			

BONE SCAN

3.	Date of Bone Scan	/	/
Not Done			

1.	Was the Investigator's assessment of objective response obtained during this visit?	Yes CR (Complete Response) PR (Partial Response) SD (Stable Disease) Progressive Disease (PD) Soft Tissue Bone No Not Evaluable (NE) No Assessment Performed
2.	Response Assessment Date	/ /
3.	Are any new bone lesions documented?	Yes Number of Lesions: No Not Evaluated

Symptomatic Deterioration

Symptomatic Deterioration is defined as a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at this visit.

4.	Did the patient experience Symptomatic Deterioration?	Yes, Date: / / No
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Skeletal-Related Events

5.	Are any new skeletal-related events documented?	Yes. Please enter details by clicking Add Entry below No Not Evaluated
6.	Type of Event	New fracture (excluding vertebral compression/rib fractures) Irradiation on bone Surgery on bone Spinal cord compression
	Location	Other, specify:
	Date of Evaluation	/ /
	Method of Evaluation	Other, specify:

Cycle 3 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 4 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit

/ /

Cycle 4 : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

1.	Did the patient receive any Study Drug during this cycle?	Yes No
2.	Did the patient receive any Prednisone during this cycle?	Yes: Was there any action taken on drug during this cycle? No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:

3. Did the patient receive any Prednisolone during this cycle?	Yes: Was there any action taken on drug during this cycle? No	Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:
4. Was the scheduled dose level for any study drug modified during this cycle?	Yes No	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 4 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 4 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24
 Site: Subject: Subject No:
 Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

1. Score:	Done Assessment / / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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Cycle 4 : ECHO - Form Version: 07-Oct-2010 00:01

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Left Ventricular Ejection Fraction	Result % Not Reported
3.	Indicate ECHO Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Unevaluable

Cycle 4 : MUGA - Form Version: 07-Oct-2010 00:05

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Ejection Fraction	Result % Not Reported
3.	Indicate MUGA Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Not Evaluable

Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3.	On the diagram, shade in the areas where you feel pain.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50
----	---	---

51
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4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

Cycle 4 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /	
	No	

Cycle 4 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 4 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all	2:A little	3:Quite a bit	4:Very much
12.	Have you felt weak?	1:Not at all	2:A little	3:Quite a bit	4:Very much
13.	Have you lacked appetite?	1:Not at all	2:A little	3:Quite a bit	4:Very much
14.	Have you felt nauseated?	1:Not at all	2:A little	3:Quite a bit	4:Very much
15.	Have you vomited?	1:Not at all	2:A little	3:Quite a bit	4:Very much
16.	Have you been constipated?	1:Not at all	2:A little	3:Quite a bit	4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all	2:A little	3:Quite a bit	4:Very much
18.	Were you tired?	1:Not at all	2:A little	3:Quite a bit	4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all	2:A little	3:Quite a bit	4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 4 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29.	How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30.	How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

6. On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today.

Cycle 4 : PHARMACOKINETICS - Form Version: 07-Oct-2010 00:07

Site: Subject: Subject No:

Millennium C21005

1. PK Sample Collection Date and Time	Collection Date / /
	Sample Time :
	Not Done

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled Hematology sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
4.	Was the scheduled PSA sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
5.	Was the scheduled Testosterone/DHEA-S sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Site: Subject: Subject No:

Millennium C21005

6. Was the scheduled ACTH, Cortisol, Corticosterone sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
7. Was the scheduled CTC Enumeration sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Cycle 4 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 5 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit	/	/
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Cycle 5 : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 5 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 5 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24
Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Score:	Done / Assessment / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3.	On the diagram, shade in the areas where you feel pain.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50
----	---	---

51
52
53

4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

Cycle 5 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /
	No

Cycle 5 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 5 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all	2:A little	3:Quite a bit	4:Very much
12.	Have you felt weak?	1:Not at all	2:A little	3:Quite a bit	4:Very much
13.	Have you lacked appetite?	1:Not at all	2:A little	3:Quite a bit	4:Very much
14.	Have you felt nauseated?	1:Not at all	2:A little	3:Quite a bit	4:Very much
15.	Have you vomited?	1:Not at all	2:A little	3:Quite a bit	4:Very much
16.	Have you been constipated?	1:Not at all	2:A little	3:Quite a bit	4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all	2:A little	3:Quite a bit	4:Very much
18.	Were you tired?	1:Not at all	2:A little	3:Quite a bit	4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all	2:A little	3:Quite a bit	4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 5 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30. How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

6. On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today.

Site: Subject: Subject No:

Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled CTC Enumeration sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Cycle 5 : IMAGING ASSESSMENT - Form Version: 07-Oct-2010 00:00

Site: Subject: Subject No:

Millennium C21005

MAGNETIC RESONANCE IMAGING (MRI)

1.	Date of MRI	/	/
Not Done			

COMPUTED TOMOGRAPHY (CT)

2.	Date of CT Scan	/	/
Not Done			

BONE SCAN

3.	Date of Bone Scan	/	/
Not Done			

1.	Was the Investigator's assessment of objective response obtained during this visit?	Yes CR (Complete Response) PR (Partial Response) SD (Stable Disease) Progressive Disease (PD) Soft Tissue Bone No Not Evaluable (NE) No Assessment Performed
2.	Response Assessment Date	/ /
3.	Are any new bone lesions documented?	Yes Number of Lesions: No Not Evaluated

Symptomatic Deterioration

Symptomatic Deterioration is defined as a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at this visit.

4.	Did the patient experience Symptomatic Deterioration?	Yes, Date: / / No
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Skeletal-Related Events

5.	Are any new skeletal-related events documented?	Yes. Please enter details by clicking Add Entry below No Not Evaluated
6.	Type of Event	New fracture (excluding vertebral compression/rib fractures) Irradiation on bone Surgery on bone Spinal cord compression
	Location	Other, specify:
	Date of Evaluation	/ /
	Method of Evaluation	Other, specify:

Cycle 5 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 6 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit	/	/
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Cycle 6 : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 6 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 6 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24
 Site: Subject: Subject No:
 Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Cycle 6 : ECOG PERFORMANCE STATUS - Form Version: 07-Oct-2010 00:02

Site: Subject: Subject No:

Millennium C21005

1. Score:	Done Assessment / / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3. On the diagram, shade in the areas where you feel pain.

1
2
3
4
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46
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51
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53

4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

Cycle 6 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 7 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit	/	/
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Cycle 7 : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 7 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 7 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

1. Score:	Done Assessment / / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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Cycle 7 : ECHO - Form Version: 07-Oct-2010 00:01

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Left Ventricular Ejection Fraction	Result % Not Reported
3.	Indicate ECHO Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Unevaluable

Cycle 7 : MUGA - Form Version: 07-Oct-2010 00:05

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Ejection Fraction	Result % Not Reported
3.	Indicate MUGA Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Not Evaluable

1.	Date/Time of ECG	/ / : Not Done
2.	Ventricular Rate	bpm Not Done
3.	PR <i>(Format: xxxxx)</i>	msec Not Done
4.	QRS <i>(Format: xxxxx)</i>	msec Not Done
5.	QT uncorrected <i>(Format: xxxxx)</i>	msec Not Done
6.	QTc Bazett	Done msec Not Done
7.	QTc Frederica	Done msec Not Done

Site: Subject: Subject No:

Millennium C21005

8. Indicate Interpretation of ECG results	<p>Within Normal Limits Abnormal-Not clinically significant Abnormal-Clinically significant</p>
---	--

Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3.	On the diagram, shade in the areas where you feel pain.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50
----	---	---

51
52
53

4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

Cycle 7 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /	
	No	

Cycle 7 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 7 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all	2:A little	3:Quite a bit	4:Very much
12.	Have you felt weak?	1:Not at all	2:A little	3:Quite a bit	4:Very much
13.	Have you lacked appetite?	1:Not at all	2:A little	3:Quite a bit	4:Very much
14.	Have you felt nauseated?	1:Not at all	2:A little	3:Quite a bit	4:Very much
15.	Have you vomited?	1:Not at all	2:A little	3:Quite a bit	4:Very much
16.	Have you been constipated?	1:Not at all	2:A little	3:Quite a bit	4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all	2:A little	3:Quite a bit	4:Very much
18.	Were you tired?	1:Not at all	2:A little	3:Quite a bit	4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all	2:A little	3:Quite a bit	4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 7 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29.	How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30.	How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

6. On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today.

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled Hematology sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
4.	Was the scheduled PSA sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
5.	Was the scheduled Testosterone/DHEA-S sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Site: Subject: Subject No:

Millennium C21005

6.	Was the scheduled ACTH, Cortisol, Corticosterone sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
7.	Was the scheduled Lipid Profile, HbA1c sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
8.	Was the scheduled CTC Enumeration sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Cycle 7 : IMAGING ASSESSMENT - Form Version: 07-Oct-2010 00:00

Site: Subject: Subject No:

Millennium C21005

MAGNETIC RESONANCE IMAGING (MRI)

1.	Date of MRI	/	/
Not Done			

COMPUTED TOMOGRAPHY (CT)

2.	Date of CT Scan	/	/
Not Done			

BONE SCAN

3.	Date of Bone Scan	/	/
Not Done			

1.	Was the Investigator's assessment of objective response obtained during this visit?	Yes CR (Complete Response) PR (Partial Response) SD (Stable Disease) Progressive Disease (PD) Soft Tissue Bone No Not Evaluable (NE) No Assessment Performed
2.	Response Assessment Date	/ /
3.	Are any new bone lesions documented?	Yes Number of Lesions: No Not Evaluated

Symptomatic Deterioration

Symptomatic Deterioration is defined as a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at this visit.

4.	Did the patient experience Symptomatic Deterioration?	Yes, Date: / / No
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Skeletal-Related Events

5.	Are any new skeletal-related events documented?	Yes. Please enter details by clicking Add Entry below No Not Evaluated
6.	Type of Event	New fracture (excluding vertebral compression/rib fractures) Irradiation on bone Surgery on bone Spinal cord compression
	Location	Other, specify:
	Date of Evaluation	/ /
	Method of Evaluation	Other, specify:

Cycle 7 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 8 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit	/	/
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<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 8 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 8 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24
 Site: Subject: Subject No:
 Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Cycle 8 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 9 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit	/	/
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<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
	<p>No</p>	
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
	<p>No</p>	

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 9 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 9 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Cycle 9 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 10 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:
Millennium C21005

1.	Date of Visit	/	/
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Cycle 10 : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 10 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 10 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24
Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

1.	Score:	Done / Assessment / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3.	On the diagram, shade in the areas where you feel pain.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50
----	---	---

51
52
53

4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

Cycle 10 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /
	No

Cycle 10 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 10 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all 2:A little 3:Quite a bit 4:Very much
12.	Have you felt weak?	1:Not at all 2:A little 3:Quite a bit 4:Very much
13.	Have you lacked appetite?	1:Not at all 2:A little 3:Quite a bit 4:Very much
14.	Have you felt nauseated?	1:Not at all 2:A little 3:Quite a bit 4:Very much
15.	Have you vomited?	1:Not at all 2:A little 3:Quite a bit 4:Very much
16.	Have you been constipated?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all 2:A little 3:Quite a bit 4:Very much
18.	Were you tired?	1:Not at all 2:A little 3:Quite a bit 4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 10 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29.	How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30.	How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

6. On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today.

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled Hematology sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
4.	Was the scheduled PSA sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
5.	Was the scheduled Testosterone/DHEA-S sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Site: Subject: Subject No:

Millennium C21005

6. Was the scheduled ACTH, Cortisol, Corticosterone sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
7. Was the scheduled CTC Enumeration sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Cycle 10 : IMAGING ASSESSMENT - Form Version: 07-Oct-2010 00:00

Site: Subject: Subject No:

Millennium C21005

MAGNETIC RESONANCE IMAGING (MRI)

1.	Date of MRI	/	/
Not Done			

COMPUTED TOMOGRAPHY (CT)

2.	Date of CT Scan	/	/
Not Done			

BONE SCAN

3.	Date of Bone Scan	/	/
Not Done			

1.	Was the Investigator's assessment of objective response obtained during this visit?	Yes CR (Complete Response) PR (Partial Response) SD (Stable Disease) Progressive Disease (PD) Soft Tissue Bone No Not Evaluable (NE) No Assessment Performed
2.	Response Assessment Date	/ /
3.	Are any new bone lesions documented?	Yes Number of Lesions: No Not Evaluated

Symptomatic Deterioration

Symptomatic Deterioration is defined as a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at this visit.

4.	Did the patient experience Symptomatic Deterioration?	Yes, Date: / / No
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Skeletal-Related Events

5.	Are any new skeletal-related events documented?	Yes. Please enter details by clicking Add Entry below No Not Evaluated
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6.	Type of Event	New fracture (excluding vertebral compression/rib fractures) Irradiation on bone Surgery on bone Spinal cord compression
	Location	Other, specify:
	Date of Evaluation	/ /
	Method of Evaluation	Other, specify:

Cycle 10 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 11 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit

/ /

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 11 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 11 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Cycle 11 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 12 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:
Millennium C21005

1.	Date of Visit	/	/
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<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 12 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 12 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Cycle 12 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 13 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:
Millennium C21005

1.	Date of Visit	/	/
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Cycle 13 : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 13 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 13 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

1.	Score:	Done / Assessment / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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Cycle 13 : ECHO - Form Version: 07-Oct-2010 00:01

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Left Ventricular Ejection Fraction	Result % Not Reported
3.	Indicate ECHO Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Unevaluable

Cycle 13 : MUGA - Form Version: 07-Oct-2010 00:05

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Ejection Fraction	Result % Not Reported
3.	Indicate MUGA Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Not Evaluable

Cycle 13 : ELECTROCARDIOGRAM - Form Version: 03-May-2013 02:32

Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of ECG	/ / : Not Done
2.	Ventricular Rate	bpm Not Done
3.	PR <i>(Format: xxxxx)</i>	msec Not Done
4.	QRS <i>(Format: xxxxx)</i>	msec Not Done
5.	QT uncorrected <i>(Format: xxxxx)</i>	msec Not Done
6.	QTc Bazett	Done msec Not Done
7.	QTc Frederica	Done msec Not Done

Cycle 13 : ELECTROCARDIOGRAM - Form Version: 03-May-2013 02:32

Site: Subject: Subject No:

Millennium C21005

8. Indicate Interpretation of ECG results	Within Normal Limits Abnormal-Not clinically significant Abnormal-Clinically significant
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Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3. On the diagram, shade in the areas where you feel pain.

1
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53

4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

Cycle 13 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /
	No

Cycle 13 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 13 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all 2:A little 3:Quite a bit 4:Very much
12.	Have you felt weak?	1:Not at all 2:A little 3:Quite a bit 4:Very much
13.	Have you lacked appetite?	1:Not at all 2:A little 3:Quite a bit 4:Very much
14.	Have you felt nauseated?	1:Not at all 2:A little 3:Quite a bit 4:Very much
15.	Have you vomited?	1:Not at all 2:A little 3:Quite a bit 4:Very much
16.	Have you been constipated?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all 2:A little 3:Quite a bit 4:Very much
18.	Were you tired?	1:Not at all 2:A little 3:Quite a bit 4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 13 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29.	How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30.	How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

- | | |
|----|---|
| 6. | On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today. |
|----|---|

Site: Subject: Subject No:

Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled Hematology sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
4.	Was the scheduled PSA sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
5.	Was the scheduled Testosterone/DHEA-S sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Site: Subject: Subject No:

Millennium C21005

6. Was the scheduled ACTH, Cortisol, Corticosterone sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
7. Was the scheduled Lipid Profile, HbA1c sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Cycle 13 : IMAGING ASSESSMENT - Form Version: 07-Oct-2010 00:00

Site: Subject: Subject No:

Millennium C21005

MAGNETIC RESONANCE IMAGING (MRI)

1.	Date of MRI	/	/
Not Done			

COMPUTED TOMOGRAPHY (CT)

2.	Date of CT Scan	/	/
Not Done			

BONE SCAN

3.	Date of Bone Scan	/	/
Not Done			

1.	Was the Investigator's assessment of objective response obtained during this visit?	Yes CR (Complete Response) PR (Partial Response) SD (Stable Disease) Progressive Disease (PD) Soft Tissue Bone No Not Evaluable (NE) No Assessment Performed
2.	Response Assessment Date	/ /
3.	Are any new bone lesions documented?	Yes Number of Lesions: No Not Evaluated

Symptomatic Deterioration

Symptomatic Deterioration is defined as a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at this visit.

4.	Did the patient experience Symptomatic Deterioration?	Yes, Date: / / No
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Skeletal-Related Events

5.	Are any new skeletal-related events documented?	Yes. Please enter details by clicking Add Entry below No Not Evaluated
----	---	--

6.	Type of Event	New fracture (excluding vertebral compression/rib fractures) Irradiation on bone Surgery on bone Spinal cord compression
	Location	Other, specify:
	Date of Evaluation	/ /
	Method of Evaluation	Other, specify:

Cycle 13 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 14 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit	/	/
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<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 14 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 14 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Cycle 14 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 15 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit

/ /

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 15 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 15 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Cycle 15 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 16 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:
Millennium C21005

1.	Date of Visit	/	/
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Cycle 16 : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 16 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 16 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24
 Site: Subject: Subject No:
 Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

1.	Score:	Done / Assessment / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3.	On the diagram, shade in the areas where you feel pain.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50
----	---	---

51
52
53

4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

Cycle 16 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /
	No

Cycle 16 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 16 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all 2:A little 3:Quite a bit 4:Very much
12.	Have you felt weak?	1:Not at all 2:A little 3:Quite a bit 4:Very much
13.	Have you lacked appetite?	1:Not at all 2:A little 3:Quite a bit 4:Very much
14.	Have you felt nauseated?	1:Not at all 2:A little 3:Quite a bit 4:Very much
15.	Have you vomited?	1:Not at all 2:A little 3:Quite a bit 4:Very much
16.	Have you been constipated?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all 2:A little 3:Quite a bit 4:Very much
18.	Were you tired?	1:Not at all 2:A little 3:Quite a bit 4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 16 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29.	How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30.	How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

6. On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today.

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled Hematology sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
4.	Was the scheduled PSA sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
5.	Was the scheduled Testosterone/DHEA-S sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Site: Subject: Subject No:

Millennium C21005

6. Was the scheduled ACTH, Cortisol, Corticosterone sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
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Cycle 16 : IMAGING ASSESSMENT - Form Version: 07-Oct-2010 00:00

Site: Subject: Subject No:

Millennium C21005

MAGNETIC RESONANCE IMAGING (MRI)

1.	Date of MRI	/	/
Not Done			

COMPUTED TOMOGRAPHY (CT)

2.	Date of CT Scan	/	/
Not Done			

BONE SCAN

3.	Date of Bone Scan	/	/
Not Done			

1.	Was the Investigator's assessment of objective response obtained during this visit?	Yes CR (Complete Response) PR (Partial Response) SD (Stable Disease) Progressive Disease (PD) Soft Tissue Bone No Not Evaluable (NE) No Assessment Performed
2.	Response Assessment Date	/ /
3.	Are any new bone lesions documented?	Yes Number of Lesions: No Not Evaluated

Symptomatic Deterioration

Symptomatic Deterioration is defined as a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at this visit.

4.	Did the patient experience Symptomatic Deterioration?	Yes, Date: / / No
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Site: Subject: Subject No:

Millennium C21005

Skeletal-Related Events

5.	Are any new skeletal-related events documented?	Yes. Please enter details by clicking Add Entry below No Not Evaluated
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6.	Type of Event	New fracture (excluding vertebral compression/rib fractures) Irradiation on bone Surgery on bone Spinal cord compression
	Location	Other, specify:
	Date of Evaluation	/ /
	Method of Evaluation	Other, specify:

Cycle 16 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 17 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:
Millennium C21005

1.	Date of Visit	/	/
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<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 17 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 17 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Cycle 17 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 18 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit

/ /

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 18 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 18 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Cycle 18 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 19 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit

/ /

Cycle 19 : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

Site: Subject: Subject No:
Millennium C21005

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:
Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle:</p> <p>Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 19 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 19 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

1.	Score:	Done / Assessment / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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Cycle 19 : ECHO - Form Version: 07-Oct-2010 00:01

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Left Ventricular Ejection Fraction	Result % Not Reported
3.	Indicate ECHO Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Unevaluable

Cycle 19 : MUGA - Form Version: 07-Oct-2010 00:05

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Ejection Fraction	Result % Not Reported
3.	Indicate MUGA Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Not Evaluable

Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3.	On the diagram, shade in the areas where you feel pain.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50
----	---	---

51
52
53

Site: Subject: Subject No:

Millennium C21005

4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

Cycle 19 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /
	No

Cycle 19 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all 2:A little 3:Quite a bit 4:Very much
12.	Have you felt weak?	1:Not at all 2:A little 3:Quite a bit 4:Very much
13.	Have you lacked appetite?	1:Not at all 2:A little 3:Quite a bit 4:Very much
14.	Have you felt nauseated?	1:Not at all 2:A little 3:Quite a bit 4:Very much
15.	Have you vomited?	1:Not at all 2:A little 3:Quite a bit 4:Very much
16.	Have you been constipated?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all 2:A little 3:Quite a bit 4:Very much
18.	Were you tired?	1:Not at all 2:A little 3:Quite a bit 4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 19 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29.	How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30.	How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

6. On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today.

Site: Subject: Subject No:
Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled Hematology sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
4.	Was the scheduled PSA sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
5.	Was the scheduled Testosterone/DHEA-S sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Site: Subject: Subject No:
Millennium C21005

6. Was the scheduled ACTH, Cortisol, Corticosterone sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
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Cycle 19 : IMAGING ASSESSMENT - Form Version: 07-Oct-2010 00:00

Site: Subject: Subject No:
Millennium C21005

MAGNETIC RESONANCE IMAGING (MRI)

1.	Date of MRI	/	/
Not Done			

COMPUTED TOMOGRAPHY (CT)

2.	Date of CT Scan	/	/
Not Done			

BONE SCAN

3.	Date of Bone Scan	/	/
Not Done			

1.	Was the Investigator's assessment of objective response obtained during this visit?	Yes CR (Complete Response) PR (Partial Response) SD (Stable Disease) Progressive Disease (PD) Soft Tissue Bone No Not Evaluable (NE) No Assessment Performed
2.	Response Assessment Date	/ /
3.	Are any new bone lesions documented?	Yes Number of Lesions: No Not Evaluated

Symptomatic Deterioration

Symptomatic Deterioration is defined as a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at this visit.

4.	Did the patient experience Symptomatic Deterioration?	Yes, Date: / / No
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Skeletal-Related Events

5.	Are any new skeletal-related events documented?	Yes. Please enter details by clicking Add Entry below No Not Evaluated
6.	Type of Event	New fracture (excluding vertebral compression/rib fractures) Irradiation on bone Surgery on bone Spinal cord compression
	Location	Other, specify:
	Date of Evaluation	/ /
	Method of Evaluation	Other, specify:

Cycle 19 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 20 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit

/ /

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
	<p>No</p>	
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
	<p>No</p>	

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 20 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 20 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Cycle 20 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 21 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:
Millennium C21005

1. Date of Visit	/	/
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<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 21 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 21 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Cycle 21 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 22 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit	/	/
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Cycle 22 : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 22 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 22 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

1. Score:	Done Assessment / / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3.	On the diagram, shade in the areas where you feel pain.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50
----	---	---

51
52
53

4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

Cycle 22 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /
	No

Cycle 22 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 22 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all 2:A little 3:Quite a bit 4:Very much
12.	Have you felt weak?	1:Not at all 2:A little 3:Quite a bit 4:Very much
13.	Have you lacked appetite?	1:Not at all 2:A little 3:Quite a bit 4:Very much
14.	Have you felt nauseated?	1:Not at all 2:A little 3:Quite a bit 4:Very much
15.	Have you vomited?	1:Not at all 2:A little 3:Quite a bit 4:Very much
16.	Have you been constipated?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all 2:A little 3:Quite a bit 4:Very much
18.	Were you tired?	1:Not at all 2:A little 3:Quite a bit 4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 22 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29.	How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30.	How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

- | | |
|----|---|
| 6. | On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today. |
|----|---|

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled Hematology sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
4.	Was the scheduled PSA sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
5.	Was the scheduled Testosterone/DHEA-S sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Site: Subject: Subject No:

Millennium C21005

6. Was the scheduled ACTH, Cortisol, Corticosterone sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
--	--

Cycle 22 : IMAGING ASSESSMENT - Form Version: 07-Oct-2010 00:00

Site: Subject: Subject No:

Millennium C21005

MAGNETIC RESONANCE IMAGING (MRI)

1.	Date of MRI	/	/
Not Done			

COMPUTED TOMOGRAPHY (CT)

2.	Date of CT Scan	/	/
Not Done			

BONE SCAN

3.	Date of Bone Scan	/	/
Not Done			

1.	Was the Investigator's assessment of objective response obtained during this visit?	Yes CR (Complete Response) PR (Partial Response) SD (Stable Disease) Progressive Disease (PD) Soft Tissue Bone No Not Evaluable (NE) No Assessment Performed
2.	Response Assessment Date	/ /
3.	Are any new bone lesions documented?	Yes Number of Lesions: No Not Evaluated

Symptomatic Deterioration

Symptomatic Deterioration is defined as a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at this visit.

4.	Did the patient experience Symptomatic Deterioration?	Yes, Date: / / No
----	---	----------------------

Skeletal-Related Events

5.	Are any new skeletal-related events documented?	Yes. Please enter details by clicking Add Entry below No Not Evaluated
6.	Type of Event	New fracture (excluding vertebral compression/rib fractures) Irradiation on bone Surgery on bone Spinal cord compression
	Location	Other, specify:
	Date of Evaluation	/ /
	Method of Evaluation	Other, specify:

Cycle 22 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 23 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:
Millennium C21005

1.	Date of Visit	/	/
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<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 23 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 23 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Cycle 23 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 24 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit

/ /

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 24 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 24 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Cycle 24 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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Cycle 25 : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit

/ /

Cycle 25 : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

Cycle 25 : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

Cycle 25 : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

1. Score:	Done Assessment / / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
-----------	--

Cycle 25 : ECHO - Form Version: 07-Oct-2010 00:01

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Left Ventricular Ejection Fraction	Result % Not Reported
3.	Indicate ECHO Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Unevaluable

Cycle 25 : MUGA - Form Version: 07-Oct-2010 00:05

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Ejection Fraction	Result % Not Reported
3.	Indicate MUGA Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Not Evaluable

Cycle 25 : ELECTROCARDIOGRAM - Form Version: 03-May-2013 02:32

Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of ECG	/ / : Not Done
2.	Ventricular Rate	bpm Not Done
3.	PR <i>(Format: xxxxx)</i>	msec Not Done
4.	QRS <i>(Format: xxxxx)</i>	msec Not Done
5.	QT uncorrected <i>(Format: xxxxx)</i>	msec Not Done
6.	QTc Bazett	Done msec Not Done
7.	QTc Frederica	Done msec Not Done

Site: Subject: Subject No:

Millennium C21005

8. Indicate Interpretation of ECG results	<p>Within Normal Limits Abnormal-Not clinically significant Abnormal-Clinically significant</p>
---	--

Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3.	On the diagram, shade in the areas where you feel pain.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50
----	---	---

51
52
53

4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

Cycle 25 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /
	No

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 25 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all 2:A little 3:Quite a bit 4:Very much
12.	Have you felt weak?	1:Not at all 2:A little 3:Quite a bit 4:Very much
13.	Have you lacked appetite?	1:Not at all 2:A little 3:Quite a bit 4:Very much
14.	Have you felt nauseated?	1:Not at all 2:A little 3:Quite a bit 4:Very much
15.	Have you vomited?	1:Not at all 2:A little 3:Quite a bit 4:Very much
16.	Have you been constipated?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all 2:A little 3:Quite a bit 4:Very much
18.	Were you tired?	1:Not at all 2:A little 3:Quite a bit 4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

Cycle 25 : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29.	How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30.	How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

6. On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today.

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled Hematology sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
4.	Was the scheduled PSA sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
5.	Was the scheduled Testosterone/DHEA-S sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Site: Subject: Subject No:

Millennium C21005

6. Was the scheduled ACTH, Cortisol, Corticosterone sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
7. Was the scheduled Lipid Profile, HbA1c sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Cycle 25 : IMAGING ASSESSMENT - Form Version: 07-Oct-2010 00:00

Site: Subject: Subject No:

Millennium C21005

MAGNETIC RESONANCE IMAGING (MRI)

1.	Date of MRI	/	/
Not Done			

COMPUTED TOMOGRAPHY (CT)

2.	Date of CT Scan	/	/
Not Done			

BONE SCAN

3.	Date of Bone Scan	/	/
Not Done			

Site: Subject: Subject No:

Millennium C21005

1.	Was the Investigator's assessment of objective response obtained during this visit?	Yes CR (Complete Response) PR (Partial Response) SD (Stable Disease) Progressive Disease (PD) Soft Tissue Bone No Not Evaluable (NE) No Assessment Performed
2.	Response Assessment Date	/ /
3.	Are any new bone lesions documented?	Yes Number of Lesions: No Not Evaluated

Symptomatic Deterioration

Symptomatic Deterioration is defined as a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at this visit.

4.	Did the patient experience Symptomatic Deterioration?	Yes, Date: / / No
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Skeletal-Related Events

5.	Are any new skeletal-related events documented?	Yes. Please enter details by clicking Add Entry below No Not Evaluated
6.	Type of Event	New fracture (excluding vertebral compression/rib fractures) Irradiation on bone Surgery on bone Spinal cord compression
	Location	Other, specify:
	Date of Evaluation	/ /
	Method of Evaluation	Other, specify:

Cycle 25 : STUDY STATUS - Form Version: 07-Oct-2010 00:04

Site: Subject: Subject No:

Millennium C21005

1. Is the patient continuing to the next cycle?	Yes No
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ADD_CYCLE : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit

/ /

ADD_CYCLE : DATE OF VISIT ADD CYCLE - Form Version: 03-May-2013 02:33

Site: Subject: Subject No:

Millennium C21005

Additional Cycle

- | | |
|----|---|
| 1. | Select the visit/interval in which additional assessments occurred: |
|----|---|

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

Site: Subject: Subject No:

Millennium C21005

<p>1. Did the patient receive any Study Drug during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>
<p>2. Did the patient receive any Prednisone during this cycle?</p>	<p>Yes: Was there any action taken on drug during this cycle?</p>	<p>Yes No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
		<p>No</p>

Site: Subject: Subject No:

Millennium C21005

3. Did the patient receive any Prednisolone during this cycle?	<p>Yes: Was there any action taken on drug during this cycle?</p> <p>No</p>	<p>Yes</p> <p>No: Dose / / Date/Time : of first dose for the cycle: Dose / / Date/Time : of last dose for the cycle:</p>
4. Was the scheduled dose level for any study drug modified during this cycle?	<p>Yes</p> <p>No</p>	

MODIFIED DOSE LEVEL

5.	Study Drug with Modified Dose Level	Study Drug Prednisone Prednisolone
	Modified Dose Level	mg
	Scheduled Dosing Day to which Modification First Applied	

ADD_CYCLE : EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:
Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date/Time	/ / : Not Done
4.	Actual Dose:	mg
5.	Action on Drug:	No Action Taken Check All that Apply: Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification:	Check All that Apply Adverse Event Other

ADD_CYCLE : PREDNISONE EXPOSURE / DOSING

Log for Treatment Cycle - Form Version: 17-Sep-2011 05:24
 Site: Subject: Subject No:
 Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken (Check All that Apply) Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1.	Dosing Day:	
2.	Scheduled Dosing Day:	
3.	Dose Date	/ / : Not Done
4.	Actual Dose	mg
5.	Action on Drug	No Action Taken Check All that Apply Reduced Prescribed Reduced Non-prescribed Increased Prescribed Increased Non-prescribed Held Interrupted Delayed Missed Discontinued Permanently
6.	Reason for Modification	Check All that Apply Adverse Event Other, Specify

Site: Subject: Subject No:

Millennium C21005

1. Score:	Done Assessment / / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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ADD_CYCLE : ECHO - Form Version: 07-Oct-2010 00:01

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Left Ventricular Ejection Fraction	Result % Not Reported
3.	Indicate ECHO Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Unevaluable

ADD_CYCLE : MUGA - Form Version: 07-Oct-2010 00:05

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Ejection Fraction	Result % Not Reported
3.	Indicate MUGA Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Not Evaluable

ADD_CYCLE : ELECTROCARDIOGRAM - Form Version: 03-May-2013 02:32

Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of ECG	/ / : Not Done
2.	Ventricular Rate	bpm Not Done
3.	PR <i>(Format: xxxxx)</i>	msec Not Done
4.	QRS <i>(Format: xxxxx)</i>	msec Not Done
5.	QT uncorrected <i>(Format: xxxxx)</i>	msec Not Done
6.	QTc Bazett	Done msec Not Done
7.	QTc Frederica	Done msec Not Done

Site: Subject: Subject No:

Millennium C21005

8. Indicate Interpretation of ECG results	Within Normal Limits Abnormal-Not clinically significant Abnormal-Clinically significant
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Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3. On the diagram, shade in the areas where you feel pain.

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Site: Subject: Subject No:

Millennium C21005

4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Site: Subject: Subject No:

Millennium C21005

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

ADD_CYCLE : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /
	No

ADD_CYCLE : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

ADD_CYCLE : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all 2:A little 3:Quite a bit 4:Very much
12.	Have you felt weak?	1:Not at all 2:A little 3:Quite a bit 4:Very much
13.	Have you lacked appetite?	1:Not at all 2:A little 3:Quite a bit 4:Very much
14.	Have you felt nauseated?	1:Not at all 2:A little 3:Quite a bit 4:Very much
15.	Have you vomited?	1:Not at all 2:A little 3:Quite a bit 4:Very much
16.	Have you been constipated?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all 2:A little 3:Quite a bit 4:Very much
18.	Were you tired?	1:Not at all 2:A little 3:Quite a bit 4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

ADD_CYCLE : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30. How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

- | | |
|----|---|
| 6. | On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today. |
|----|---|

Site: Subject: Subject No:

Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled Hematology sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
4.	Was the scheduled PSA sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
5.	Was the scheduled Testosterone/DHEA-S sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Site: Subject: Subject No:

Millennium C21005

6. Was the scheduled ACTH, Cortisol, Corticosterone sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
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Site: Subject: Subject No:

Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled Hematology sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
4.	Was the scheduled PSA sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
5.	Was the scheduled Testosterone/DHEA-S sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Site: Subject: Subject No:

Millennium C21005

6.	Was the scheduled ACTH, Cortisol, Corticosterone sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
7.	Was the scheduled Lipid Profile, HbA1c sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Site: Subject: Subject No:

Millennium C21005

MAGNETIC RESONANCE IMAGING (MRI)

1.	Date of MRI	/	/
Not Done			

COMPUTED TOMOGRAPHY (CT)

2.	Date of CT Scan	/	/
Not Done			

BONE SCAN

3.	Date of Bone Scan	/	/
Not Done			

1.	Was the Investigator's assessment of objective response obtained during this visit?	Yes CR (Complete Response) PR (Partial Response) SD (Stable Disease) Progressive Disease (PD) Soft Tissue Bone No Not Evaluable (NE) No Assessment Performed
2.	Response Assessment Date	/ /
3.	Are any new bone lesions documented?	Yes Number of Lesions: No Not Evaluated

Symptomatic Deterioration

Symptomatic Deterioration is defined as a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at this visit.

4.	Did the patient experience Symptomatic Deterioration?	Yes, Date: / / No
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Skeletal-Related Events

5.	Are any new skeletal-related events documented?	Yes. Please enter details by clicking Add Entry below No Not Evaluated
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6.	Type of Event	New fracture (excluding vertebral compression/rib fractures) Irradiation on bone Surgery on bone Spinal cord compression
	Location	Other, specify:
	Date of Evaluation	/ /
	Method of Evaluation	Other, specify:

1.	Has the patient reported any Adverse Events?	Yes No
2.	Has the patient reported any Concomitant Medications?	Yes No
3.	Has the patient reported any Concomitant Procedures?	Yes No
4.	Has the patient reported any Narcotic Pain Medications within the 24 hour period prior to completing any Brief Pain Inventory Short Form?	Yes No
5.	Did the patient develop a non-localized rash of grade 2 or higher?	Yes No

1.	Sequence Number	
2.	Adverse Event	
3.	Is the event serious? (If SAE is Yes, submit a completed SAE report to the Millennium Safety Group or designee.)	Yes No
4.	Onset Date	/ /
5.	End Date	/ /
6.	Is there a reasonable possibility that the AE was associated with the study medication?	Yes No
7.	Intensity	Grade 1 Grade 2 Grade 3 Grade 4 Grade 5

8.	Action Taken	No Action Taken Dose held Dose interrupted Dose reduced Dose increased Dose incomplete Dose delayed Drug (or Dose) discontinued permanently Concomitant medication administered Concomitant procedure performed Discontinued from study
9.	Outcome	Resolved Resolved with Sequelae Unresolved Death Related to disease under study or complications thereof? Not Related to disease under study or complications thereof? Unknown
10.	Low Level Term - Code	
11.	Low Level Term - Name	
12.	Preferred Term - Code	
13.	Preferred Term - Name	
14.	High Level Term - Code	

15.	High Level Term - Name	
16.	High Level Group Term - Code	
17.	High Level Group Term - Name	
18.	System Organ Class - Name	
19.	SOC - Name 2	
20.	SOC - Name 3	
21.	SOC - Name 4	
22.	SOC - Name 5	
23.	SOC - Name 6	
24.	Current MedDRA Version	
25.	Coding Status	
26.	Coding Date	/ /
27.	Re-Code Flag	

Site: Subject: Subject No:

Millennium C21005

28.	Clear coding	Clear coding
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1.	Sequence Number	
2.	Medication	
3.	Dose	
4.	Units	
5.	Frequency	
6.	Route	
7.	Date Started <i>(dd/mmm/yyyy)</i>	/ /
8.	Date Stopped <i>(dd/mmm/yyyy)</i>	/ / Ongoing
9.	Clinical Indication <i>(If related to Adverse Event, associate this ConMed with the appropriate AE record(s).)</i>	Adverse Event Prophylaxis Medical History Treatment for condition under study
10.	Specify Reason for Indication	
11.	Brand Name	

12.	Drug Record Number	
13.	Drug Sequence Number - 1	
14.	Drug Sequence Number - 2	
15.	Generic Name	
16.	Generic Record Number	
17.	Generic Sequence Number - 1	
18.	Generic Sequence Number - 2	
19.	Anatomical Therapeutic Classification	
20.	Anatomical Therapeutic Description	
21.	WHODRUG Version - Date	
22.	Coding Status	
23.	Coding Date	/ /
24.	Re-Code Flag	

Site: Subject: Subject No:

Millennium C21005

25. Clear coding

Clear coding

Site: Subject: Subject No:

Millennium C21005

1.	Sequence Number	
2.	Procedure	
3.	Date of Procedure <i>(dd/mmm/yyyy)</i>	/ /
4.	Reason Code	Adverse Event Prophylaxis Medical History Treatment for condition under study
5.	Specify Reason	

Site: Subject: Subject No:

Millennium C21005

1.	Sequence Number	
2.	Narcotic Medication Name	
3.	Total Daily Dose	
4.	Units	g mg mcg (micrograms) Other, specify weight unit
5.	Route	
6.	Date Started (dd/mmm/yyyy)	/ /
7.	Date Stopped (dd/mmm/yyyy)	/ /
8.	Type of Pain	Cancer related bone pain Cancer related pain Non-cancer related bone pain Non-cancer related pain
9.	Brand Name	
10.	Drug Record Number	

Site: Subject: Subject No:

Millennium C21005

11.	Drug Sequence Number - 1	
12.	Drug Sequence Number - 2	
13.	Generic Name	
14.	Generic Record Number	
15.	Generic Sequence Number - 1	
16.	Generic Sequence Number - 2	
17.	Anatomical Therapeutic Classification	
18.	Anatomical Therapeutic Description	
19.	WHODRUG Version - Date	
20.	Coding Status	
21.	Coding Date	/ /
22.	Re-Code Flag	
23.	Clear coding	Clear coding

Site: Subject: Subject No:

Millennium C21005

1.	Onset Date	/	/
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Rash Assessment

2.	Sequence Number	
	Date of Assessment	/ /
	Overall Symptoms Rate	0:No symptoms 1:Mild symptoms; some itching, aware of rash a few times during day 2:Moderate symptoms; frequent itching, bothersome frequently during the day 3:Severe symptoms; generalized itching most of the time, interferes with normal activity, incompletely relieved by treatment, interferes frequently with sleep

Rash Assessment (Cont.)

2. (Cont.)	Symptom(s) related to rash	Select all that apply: Pruritus Skin pain(s) Abdominal pain Diarrhea Wheezing Dyspnea/Shortness of Breath Increased Fatigue Malaise New joint pain(s) New joint swelling(s) Edema Not Applicable
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Rash Assessment (Cont.)

2. (Cont.)	<p>Physical characteristic(s) of rash</p> <ul style="list-style-type: none"> <input type="checkbox"/> Erythema <input type="checkbox"/> Macules <input type="checkbox"/> Papules <input type="checkbox"/> Nodules <input type="checkbox"/> Plaques <input type="checkbox"/> Pustules <input type="checkbox"/> Vesicles <input type="checkbox"/> Bullae <input type="checkbox"/> Ulcers <input type="checkbox"/> Urticaria <input type="checkbox"/> Angioedema <input type="checkbox"/> Purpura <input type="checkbox"/> Scaling <input type="checkbox"/> Desquamation <input type="checkbox"/> Skin necrosis <input type="checkbox"/> Epidermal necrolysis <input type="checkbox"/> Tenderness <input type="checkbox"/> Pruritus <input type="checkbox"/> Pain <input type="checkbox"/> Skin target lesions 	
What is the dominant physical characteristic of the rash?		

Rash Assessment (Cont.)

2. (Cont.)	Areas of Involvement	Select all that apply: Face Eye Mouth/Lip Scalp Neck Pharynx Larynx Tongue Right Arm Skin Left Arm Skin Right Leg Skin Left Leg Skin Right Palm/Hand Left Palm/Hand Right Sole/Foot Left Sole/Foot Back Chest/Abdominal Skin Buttocks Perineum/Genitals Other
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Rash Assessment (Cont.)

2. (Cont.)	Was the rash eruption following more than usual sun or ultraviolet light exposure (i.e. sunbathing, tanning beds)?	Yes No
	Was there mucous membrane involvement?	Yes No

Site: Subject: Subject No:

Millennium C21005

Visit Date

1.	Date of Visit	/	/
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Additional Assessments

2.	Select the visit/interval in which additional assessments occurred:	Unscheduled Is this visit due to an AE? Yes No
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Site: Subject: Subject No:

Millennium C21005

1. Select the forms for which additional assessments were done for the specified visit:	ECOG Performance Status Sample Collection Adhoc Local Chemistry Local Hematology Electrocardiogram Local PSA Unscheduled PK Investigator Response Assessment Imaging Assessment ECHO MUGA Vital Signs Brief Pain Inventory EORTC QLQ-C30 EQ-5D Questionnaire PI Signature
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UNSCHEDULED : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

UNSCHEDULED : ECOG PERFORMANCE STATUS - Form Version: 07-Oct-2010 00:02

Site: Subject: Subject No:

Millennium C21005

1. Score:	Done Assessment / / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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UNSCHEDULED : ECHO - Form Version: 07-Oct-2010 00:01

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Left Ventricular Ejection Fraction	Result % Not Reported
3.	Indicate ECHO Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Unevaluable

UNSCHEDULED : MUGA - Form Version: 07-Oct-2010 00:05

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Ejection Fraction	Result % Not Reported
3.	Indicate MUGA Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Not Evaluable

UNSCHEDULED : ELECTROCARDIOGRAM - Form Version: 03-May-2013 02:32

Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of ECG	/ / : Not Done
2.	Ventricular Rate	bpm Not Done
3.	PR <i>(Format: xxxxx)</i>	msec Not Done
4.	QRS <i>(Format: xxxxx)</i>	msec Not Done
5.	QT uncorrected <i>(Format: xxxxx)</i>	msec Not Done
6.	QTc Bazett	Done msec Not Done
7.	QTc Frederica	Done msec Not Done

UNSCHEDULED : ELECTROCARDIOGRAM - Form Version: 03-May-2013 02:32

Site: Subject: Subject No:

Millennium C21005

8. Indicate Interpretation of ECG results	<p>Within Normal Limits Abnormal-Not clinically significant Abnormal-Clinically significant</p>
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UNSCHEDULED : BLOOD CHEMISTRY - Form Version: 17-Sep-2011 05:25

Site: Subject: Subject No:

Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Laboratory Name	
3.	Sodium	Result Unit Low Range High Range Not Done
4.	Potassium	Result Unit Low Range High Range Not Done
5.	Chloride	Result Unit Low Range High Range Not Done

UNSCHEDULED : BLOOD CHEMISTRY - Form Version: 17-Sep-2011 05:25

Site: Subject: Subject No:

Millennium C21005

6.	CO ₂	Result Unit Low Range High Range Not Done
7.	BUN	Result Unit Low Range High Range Not Done
8.	Creatinine	Result Unit Low Range High Range Not Done
9.	Total Bilirubin	Result Unit Low Range High Range Not Done

10.	AST/SGOT	Result Unit Low Range High Range Not Done
11.	ALT/SGPT	Result Unit Low Range High Range Not Done
12.	Alkaline Phosphatase	Result Unit Low Range High Range Not Done
13.	Magnesium	Result Unit Low Range High Range Not Done

UNSCHEDULED : BLOOD CHEMISTRY - Form Version: 17-Sep-2011 05:25

Site: Subject: Subject No:

Millennium C21005

14.	Calcium	Result Unit Low Range High Range Not Done
15.	Glucose	Result Unit Low Range High Range Not Done
16.	Uric Acid	Result Unit Low Range High Range Not Done
17.	Albumin	Result Unit Low Range High Range Not Done

18.	Phosphorus (Phosphate)	Result Unit Low Range High Range Not Done
19.	Cholesterol	Result Unit Low Range High Range Not Done
20.	LDH	Result Unit Low Range High Range Not Done
21.	Triglycerides	Result Unit Low Range High Range Not Done

UNSCHEDULED : BLOOD CHEMISTRY - Form Version: 17-Sep-2011 05:25

Site: Subject: Subject No:

Millennium C21005

22.	HDL	Result Unit Low Range High Range Not Done
23.	LDL	Result Unit Low Range High Range Not Done
24.	Amylase	Result Unit Low Range High Range Not Done
25.	Lipase	Result Unit Low Range High Range Not Done

ENDOCRINOLOGY

26.	DHEA-S	Result Unit Low Range High Range Not Done
27.	Testosterone	Result Unit Low Range High Range Not Done
28.	Cortisol	Result Unit Low Range High Range Not Done
29.	Corticosterone	Result Unit Low Range High Range Not Done

ENDOCRINOLOGY (Cont.)

30.	ACTH	Result Unit Low Range High Range Not Done
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Site: Subject: Subject No:

Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Laboratory Name	
3.	White Blood Cell Count	Result Unit Low Range High Range Not Done
4.	Hemoglobin	Result Unit Low Range High Range Not Done
5.	Hematocrit	Result Unit Low Range High Range Not Done

6.	Platelet Count	Result Unit Low Range High Range Not Done
7.	Lymphocytes	Result Unit Low Range High Range Not Done
8.	Monocytes	Result Unit Low Range High Range Not Done
9.	Eosinophils	Result Unit Low Range High Range Not Done

10.	Basophils	Result Unit Low Range High Range Not Done
11.	Neutrophils	Result Unit Low Range High Range Not Done
12.	ANC	Result Unit Low Range High Range Not Done
13.	HbA1c	Result Unit Low Range High Range Not Done

UNSCHEDULED : BRIEF PAIN INVENTORY SHORT FORM - Form Version: 17-Sep-2011 05:23

Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3.	On the diagram, shade in the areas where you feel pain.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50
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51
52
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Site: Subject: Subject No:

Millennium C21005

4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Site: Subject: Subject No:

Millennium C21005

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

UNSCHEDULED : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /	No
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UNSCHEDEDULED : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

UNSCHEDULED : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all 2:A little 3:Quite a bit 4:Very much
12.	Have you felt weak?	1:Not at all 2:A little 3:Quite a bit 4:Very much
13.	Have you lacked appetite?	1:Not at all 2:A little 3:Quite a bit 4:Very much
14.	Have you felt nauseated?	1:Not at all 2:A little 3:Quite a bit 4:Very much
15.	Have you vomited?	1:Not at all 2:A little 3:Quite a bit 4:Very much
16.	Have you been constipated?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all 2:A little 3:Quite a bit 4:Very much
18.	Were you tired?	1:Not at all 2:A little 3:Quite a bit 4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

UNSCHEDEDULED : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30. How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

6. On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today.

UNSCHEDULED : PK UNSCHEDULED - Form Version: 07-Oct-2010 00:01

Site: Subject: Subject No:

Millennium C21005

1. PK Sample Collection Date and Time	Collection Date	/	/
	Sample Time	:	

UNSCHEDULED : SAMPLE COLLECTION

ADDITIONAL LABS (SAMPLES) - Form Version: 07-Oct-2010 00:05

Site: Subject: Subject No:

Millennium C21005

1.	Sequence Number	
2.	Lab Test	
3.	Sample Collection Date	/ /

Site: Subject: Subject No:

Millennium C21005

MAGNETIC RESONANCE IMAGING (MRI)

1.	Date of MRI	/	/
Not Done			

COMPUTED TOMOGRAPHY (CT)

2.	Date of CT Scan	/	/
Not Done			

BONE SCAN

3.	Date of Bone Scan	/	/
Not Done			

Site: Subject: Subject No:

Millennium C21005

1.	Was the Investigator's assessment of objective response obtained during this visit?	Yes CR (Complete Response) PR (Partial Response) SD (Stable Disease) Progressive Disease (PD) Soft Tissue Bone No Not Evaluable (NE) No Assessment Performed
2.	Response Assessment Date	/ /
3.	Are any new bone lesions documented?	Yes Number of Lesions: No Not Evaluated

Symptomatic Deterioration

Symptomatic Deterioration is defined as a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at this visit.

4.	Did the patient experience Symptomatic Deterioration?	Yes, Date: / / No
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Site: Subject: Subject No:

Millennium C21005

Skeletal-Related Events

5.	Are any new skeletal-related events documented?	Yes. Please enter details by clicking Add Entry below No Not Evaluated
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6.	Type of Event	New fracture (excluding vertebral compression/rib fractures) Irradiation on bone Surgery on bone Spinal cord compression
	Location	Other, specify:
	Date of Evaluation	/ /
	Method of Evaluation	Other, specify:

Site: Subject: Subject No:

Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Laboratory Name	
3.	Result	
4.	Units	U/ml ng/ml Other, specify:

UNSCHEDULED : PI SIGNATURE - Form Version: 03-May-2013 02:28

Site: Subject: Subject No:
Millennium C21005

Interim Signature

1.	Ready for PI Signature	Ready for PI Signature
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End of Treatment : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit

/ /

End of Treatment : VITAL SIGNS - Form Version: 03-May-2013 02:29

Site: Subject: Subject No:

Millennium C21005

1.	Date of Vital Signs	/ /
2.	Weight <i>(Format: xxx.x)</i>	kg lbs Not Done
3.	Temperature <i>(Format: xxx.x)</i>	C F Not Done
4.	Heart Rate	bpm Not Done
5.	Systolic/Diastolic Blood Pressure	Done / mmHg Not Done

1.	Score:	Done Assessment / / Date: 0=Normal activity. Fully active, able to carry on all predisease performance without restriction. 1=Symptoms but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). 2=In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. 4=100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. Not Done
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End of Treatment : ECHO - Form Version: 07-Oct-2010 00:01

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Left Ventricular Ejection Fraction	Result % Not Reported
3.	Indicate ECHO Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Unevaluable

End of Treatment : MUGA - Form Version: 07-Oct-2010 00:05

Site: Subject: Subject No:

Millennium C21005

1.	Date of Assessment	/ / Not Done
2.	Ejection Fraction	Result % Not Reported
3.	Indicate MUGA Result	Within Normal Limits Abnormal, Not Clinically Significant Abnormal, Clinically Significant: Describe: Not Evaluable

End of Treatment : ELECTROCARDIOGRAM - Form Version: 03-May-2013 02:32

Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of ECG	/ / : Not Done
2.	Ventricular Rate	bpm Not Done
3.	PR <i>(Format: xxxxx)</i>	msec Not Done
4.	QRS <i>(Format: xxxxx)</i>	msec Not Done
5.	QT uncorrected <i>(Format: xxxxx)</i>	msec Not Done
6.	QTc Bazett	Done msec Not Done
7.	QTc Frederica	Done msec Not Done

End of Treatment : ELECTROCARDIOGRAM - Form Version: 03-May-2013 02:32
Site: Subject: Subject No:
Millennium C21005

8. Indicate Interpretation of ECG results	Within Normal Limits Abnormal-Not clinically significant Abnormal-Clinically significant
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End of Treatment : BRIEF PAIN INVENTORY SHORT FORM - Form Version: 17-Sep-2011 05:23

Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3.	On the diagram, shade in the areas where you feel pain.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50
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51
52
53

4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

End of Treatment : BRIEF PAIN INVENTORY SHORT FORM - Form Version: 17-Sep-2011 05:23

Site: Subject: Subject No:

Millennium C21005

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

End of Treatment : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /	No
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End of Treatment : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
 Site: Subject: Subject No:
 Millennium C21005

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

End of Treatment : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all	2:A little	3:Quite a bit	4:Very much
12.	Have you felt weak?	1:Not at all	2:A little	3:Quite a bit	4:Very much
13.	Have you lacked appetite?	1:Not at all	2:A little	3:Quite a bit	4:Very much
14.	Have you felt nauseated?	1:Not at all	2:A little	3:Quite a bit	4:Very much
15.	Have you vomited?	1:Not at all	2:A little	3:Quite a bit	4:Very much
16.	Have you been constipated?	1:Not at all	2:A little	3:Quite a bit	4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all	2:A little	3:Quite a bit	4:Very much
18.	Were you tired?	1:Not at all	2:A little	3:Quite a bit	4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all	2:A little	3:Quite a bit	4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

End of Treatment : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29.	How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30.	How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

End of Treatment : EQ-5D Health Questionnaire - Form Version: 07-Oct-2010 00:02

Site: Subject: Subject No:

Millennium C21005

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

End of Treatment : EQ-5D Health Questionnaire - Form Version: 07-Oct-2010 00:02

Site: Subject: Subject No:

Millennium C21005

6. On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today.

End of Treatment : SAMPLE COLLECTION - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:

Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled Hematology sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
3.	Was the scheduled Serum Chemistry sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
4.	Was the scheduled PSA sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
5.	Was the scheduled Testosterone/DHEA-S sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

End of Treatment : SAMPLE COLLECTION - Form Version: 17-Sep-2011 05:22

Site: Subject: Subject No:

Millennium C21005

6. Was the scheduled ACTH, Cortisol, Corticosterone sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done
7. Was the scheduled CTC Enumeration sample obtained on the same collection date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

End of Treatment : TREATMENT TERMINATION - Form Version: 20-Dec-2011 04:34

Site: Subject: Subject No:

Millennium C21005

1.	Did the patient complete study treatment per the protocol?	Yes Adverse Event Disease Progression Withdrawal by Subject No
2.	Reason off treatment (select primary reason):	Initiation of Alternate Antineoplastic Therapy Protocol Violation Study Terminated by Sponsor Lost to follow-up Symptomatic Deterioration Other, specify:
3.	Will the patient participate in Progression Free Survival Follow-up?	Yes No

Site: Subject: Subject No:

Millennium C21005

1.	Date of Visit	/	/
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Alternate Therapy

2.	Did the patient start an alternate therapy?	Alternate Therapy Indicate type of alternate therapy: Indicate date started: (dd/mmm/yyyy) / / No
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Site: Subject: Subject No:

Millennium C21005

1.	Date/Time of BPI	/ / : Not Done
2.	Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?	Yes No

3. On the diagram, shade in the areas where you feel pain.

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Site: Subject: Subject No:

Millennium C21005

4.	Put an X on the area that hurts the most.	
5.	Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.	
6.	Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.	
7.	Please rate your pain by circling the one number that best describes your pain on the average.	
8.	Please rate your pain by circling the one number that tells how much pain you have right now.	
9.	What treatments or medications are you receiving for your pain?	Patient is receiving treatments and medications for their pain. Record all treatments and medications in the appropriate Concomitant Medications and/or Concomitant Procedures form. Patient is not receiving any treatments or medications for their pain.
10.	In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

11.	General Activity	
12.	Mood	

Circle the one number that describes how, during the past 24 hours, pain has interfered with your: (Cont.)

13.	Walking Ability	
14.	Normal Work (includes both work outside the home and housework)	
15.	Relations with other people	
16.	Sleep	
17.	Enjoyment of life	

STFU : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC QLQ-C30 (VERSION 3))
Site: Subject: Subject No:
Millennium C21005

Form Version: 07-Oct-2010 00:08

1. Was a questionnaire obtained?	Yes / /
	No

Site: Subject: Subject No:

Millennium C21005

1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1:Not at all 2:A little 3:Quite a bit 4:Very much
2.	Do you have any trouble taking a LONG walk?	1:Not at all 2:A little 3:Quite a bit 4:Very much
3.	Do you have any trouble taking a SHORT walk outside of the house?	1:Not at all 2:A little 3:Quite a bit 4:Very much
4.	Do you need to stay in bed or a chair during the day?	1:Not at all 2:A little 3:Quite a bit 4:Very much
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

6.	Were you limited in doing either your work or other daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
8.	Were you short of breath?	1:Not at all 2:A little 3:Quite a bit 4:Very much
9.	Have you had pain?	1:Not at all 2:A little 3:Quite a bit 4:Very much
10.	Did you need to rest?	1:Not at all 2:A little 3:Quite a bit 4:Very much

STFU : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

During the past week: (Cont.)

11.	Have you had trouble sleeping?	1:Not at all 2:A little 3:Quite a bit 4:Very much
12.	Have you felt weak?	1:Not at all 2:A little 3:Quite a bit 4:Very much
13.	Have you lacked appetite?	1:Not at all 2:A little 3:Quite a bit 4:Very much
14.	Have you felt nauseated?	1:Not at all 2:A little 3:Quite a bit 4:Very much
15.	Have you vomited?	1:Not at all 2:A little 3:Quite a bit 4:Very much
16.	Have you been constipated?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week:

17.	Have you had diarrhea?	1:Not at all 2:A little 3:Quite a bit 4:Very much
18.	Were you tired?	1:Not at all 2:A little 3:Quite a bit 4:Very much
19.	Did pain interfere with your daily activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much

During the past week: (Cont.)

20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1:Not at all 2:A little 3:Quite a bit 4:Very much
21.	Did you feel tense?	1:Not at all 2:A little 3:Quite a bit 4:Very much
22.	Did you worry?	1:Not at all 2:A little 3:Quite a bit 4:Very much
23.	Did you feel irritable?	1:Not at all 2:A little 3:Quite a bit 4:Very much
24.	Did you feel depressed?	1:Not at all 2:A little 3:Quite a bit 4:Very much
25.	Have you had difficulty remembering things?	1:Not at all 2:A little 3:Quite a bit 4:Very much
26.	Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all 2:A little 3:Quite a bit 4:Very much
27.	Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all 2:A little 3:Quite a bit 4:Very much
28.	Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all 2:A little 3:Quite a bit 4:Very much

STFU : EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER - Form Version: 07-Oct-2010 00:00
Site: Subject: Subject No:
Millennium C21005

For the following questions please circle the number between 1 and 7 that best applies to you

29.	How would you rate your overall HEALTH during the past week?	1:Very poor 2 3 4 5 6 7:Excellent
30.	How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor 2 3 4 5 6 7:Excellent

1.	Mobility	1 = I have no problems in walking about 2 = I have some problems in walking about 3 = I am confined to bed
2.	Self-Care	1 = I have no problems with self-care 2 = I have some problems washing or dressing myself 3 = I am unable to wash or dress myself
3.	Usual Activities	1 = I have no problems with performing my usual activities 2 = I have some problems with performing my usual activities 3 = I am unable to perform my usual activities
4.	Pain/Discomfort	1 = I have no pain or discomfort 2 = I have moderate pain or discomfort 3 = I have extreme pain or discomfort
5.	Anxiety/Depression	1 = I am not anxious or depressed 2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

- | | |
|----|---|
| 6. | On a scale of 0 to 100, where 0 is the worst imaginable health state and 100 is the best imaginable health state, please indicate how good or bad your own health is today. |
|----|---|

Site: Subject: Subject No:

Millennium C21005

1.	Sample Collection Date	/ / Not Done
2.	Was the scheduled PSA sample obtained on the same Sample Collection Date?	Yes, same Sample Collection Date as specified in Question 1 No, provide date: / / Not Done

Site: Subject: Subject No:

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MAGNETIC RESONANCE IMAGING (MRI)

1.	Date of MRI	/	/
Not Done			

COMPUTED TOMOGRAPHY (CT)

2.	Date of CT Scan	/	/
Not Done			

BONE SCAN

3.	Date of Bone Scan	/	/
Not Done			

1.	Was the Investigator's assessment of objective response obtained during this visit?	Yes CR (Complete Response) PR (Partial Response) SD (Stable Disease) Progressive Disease (PD) Soft Tissue Bone No Not Evaluable (NE) No Assessment Performed
2.	Response Assessment Date	/ /
3.	Are any new bone lesions documented?	Yes Number of Lesions: No Not Evaluated

Symptomatic Deterioration

Symptomatic Deterioration is defined as a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at this visit.

4.	Did the patient experience Symptomatic Deterioration?	Yes, Date: / / No
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Skeletal-Related Events

5.	Are any new skeletal-related events documented?	Yes. Please enter details by clicking Add Entry below No Not Evaluated
6.	Type of Event	New fracture (excluding vertebral compression/rib fractures) Irradiation on bone Surgery on bone Spinal cord compression
	Location	Other, specify:
	Date of Evaluation	/ /
	Method of Evaluation	Other, specify:

MEDICAL ENCOUNTER : Medical Encounter - Form Version: 07-Oct-2010 00:06

Site: Subject: Subject No:

Millennium C21005

1.	Has the subject been hospitalized or visited an outpatient clinic since screening or at any time up through short-term follow-up, other than for scheduled visits or for scheduled laboratory specimens?	Yes. Please enter details by clicking Add Entry below No
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Hospitalization/Outpatient Visit

2.	Sequence Number	
	Was the hospitalization/outpatient visit ongoing at study start?	Yes No: / / Admission/Visit Date
	Was the hospitalization ongoing at study end? For hospitalization only	Yes No: Discharge / / Date

Hospitalization/Outpatient Visit (Cont.)

2. (Cont.)	Visit type	<p>Hospitalization, please select all that apply</p> <p>Acute care unit (other than ICU)</p> <p>Palliative care unit</p> <p>Hospice</p> <p>Intensive care unit</p> <p>Emergency room</p> <p>Outpatient, please select all that apply</p> <p>Study physician or study site</p> <p>Other physician or clinic</p> <p>Laboratory department</p> <p>Other, specify:</p>
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Hospitalization/Outpatient Visit (Cont.)

2. (Cont.)	<p>Reason</p> <p>Medication Procedure Adverse Event/Toxicity Disease-related signs and symptoms Chemotherapy Radiotherapy Preplanned surgery Other, specify:</p>	
	<p>Did the subject miss any days of work or other activity?</p> <p>Yes Days missed</p> <p>No</p>	
	<p>Did the subject's caregiver miss any days of work or other activity?</p> <p>Yes Days missed</p> <p>No Not Applicable</p>	

Long-Term Follow-up Assessment

1.	Sequence Number	
2.	Date of Visit	/ /
3.	Follow-up conducted by	Telephone Office Visit E-Mail Other (specify)
4.	Check all of the responses that apply	Patient alive with no change in status from prior visit Patient refused further follow-up Lost to follow-up Indicate last known contact date: (dd/mmm/yyyy) / / Alternate Therapy Indicate type of alternate therapy: Indicate date started: (dd/mmm/yyyy) / / Patient death (please complete Death eCRF) Sponsor termination of study Patient withdrew consent

End of Study : DATE OF VISIT - Form Version: 03-May-2013 02:30

Site: Subject: Subject No:

Millennium C21005

1. Date of Visit	/	/
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End of Study : END OF STUDY - Form Version: 07-Oct-2010 00:05

Site: Subject: Subject No:

Millennium C21005

1.	Did the patient complete the study per the protocol?	Yes Death Study Terminated by Sponsor No
2.	Reason for end of study	Withdrawal by Subject Lost to Follow-up Other, specify:

End of Study : DEATH REPORT - Form Version: 07-Oct-2010 00:05

Site: Subject: Subject No:

Millennium C21005

1.	Date of Death	/	/
2.	Primary Cause of Death	Related to Disease under Study (Prostate Cancer or Complications Thereof) Other, specify:	

WORKFLOW : Workflow Reset - Form Version: 17-Sep-2011 05:25

Site: Subject: Subject No:

Millennium C21005

1. Workflow reset checkbox	Yes
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