Bone Mets Project Data Elements

DEMOGRAPHICS

Data Elements	Options
• Provider	• First/Last
• Date of initial Radiation/Oncology consult	• mm/dd/yyyy
• Date of Birth	• mm/yyyy
• Gender *(Select only one)*	• Male/Female
• Race *(Select only one)*	• American Indian/Alaska Native • Asian • Native Hawaiian or Other Pacific Islander • Black or African American • White • Arab/Middle Eastern • Unknown or not reported • Other (free text)
• Medical Insurance *(Check all that apply)*	• No insurance/self-pay • Medicare(all) • Medicare Advantage-BCN • Medicare Advantage-BCBSM • Medicaid-Straight • Medicaid -HMO • Other Payer (government) • Other Payer (Michigan and outstate) • BCBSM-Michigan • BCN- Michigan • Commercial-HMO

• Current Marital Status *(Select only one)*	• Married/ Domestic Partner • Divorced • Never Married • Separated • Widowed • Living with someone • Single
• Primary Cancer Type *(Select only one)*	• Breast Cancer • Prostate Cancer • Melanoma • Renal Cell Cancer • Non-Small Cell Lung Cancer • Small Cell Lung Cancer • Other Primary Cancer Type (free text)

M1 CDA: Bone Mets Baseline Clinical Data Form

Time points: Pre-Treatment

Data Elements	Options
Weight (specify lbs. or kg)	_____ (lbs. or kg)
BMI or Height (specify inches or cm):	_____ or _____ (inches or cm)
Date of initial cancer diagnosis	_____ (mm/yyyy)
History of previous radiation therapy to the same anatomic site(s) being treated?	• Yes • No
Physician documentation of spinal cord compression, cauda compression, or radicular pain at the site being treated?	• Yes • No
Prior Surgery at the site being treated?	• Resection • Stabilization • Resection with stabilization

	• Other, please specify_____ • N/A
Femoral axis cortical involvement >3cm in length?	• Yes • No • N/A
Have palliative care services evaluated the patient?	• Yes • No
Is the patient planning to enter hospice within 7 days of the end of treatment?	• Yes • No
In addition to bone, is there metastatic disease in the CNS or viscera? ➢ If yes, please specify where:*(check all that apply)*	• Yes • No • Adrenal Glands • Brain • Liver • Lung • Lymph Nodes • Other, please specify where: _____
Reported overall pain intensity on a scale of 0-10)	_____ (0-10)
Bone-Modifying Agents	• Yes • No
Steroids	• Yes • No
NSAIDS/ Tylenol	• Yes • No

MICHIGAN RADIATION ONCOLOGY QUALITY CONSORTIUM

MROQC Bone Mets Data Elements Guide

Date of first fraction	_____ (mm/dd/yyyy)
Date of last fraction	_____ (mm/dd/yyyy)
At the time of the first fraction, was the patient an inpatient or outpatient?	• Inpatient • Outpatient

Comorbidities

Does the patient have:	YES	NO	Does the patient have:	YES	NO
Hypertension?	❑	❑	Hemiplegia?	❑	❑
Diabetes mellitus?	❑	❑	Leukemia?	❑	❑
Scleroderma?	❑	❑	Malignant lymphoma?	❑	❑
Rheumatoid Arthritis?	❑	❑	Myocardial infarction?	❑	❑
Lupus?	❑	❑	Peripheral vascular disease?	❑	❑
Cerebrovascular disease?	❑	❑	Ulcer disease?	❑	❑
Chronic pulmonary disease?	❑	❑	Liver disease?	❑	❑
Congestive heart failure?	❑	❑	Renal disease?	❑	❑
Connective tissue disease?	❑	❑	Malignant solid tumor	❑	❑
Confusion?	❑	❑			

Karnofsky Performance Scale (circle response)

100	Normal no complaints; no evidence of disease.
90	Able to carry on normal activity; minor signs or symptoms of disease.
80	Normal activity with effort; some signs or symptoms of disease.
70	Cares for self; unable to carry on normal activity or to do active work.
60	Requires occasional assistance, but is able to care for most of his personal needs.
50	Requires considerable assistance and frequent medical care.
40	Disabled; requires special care and assistance.
30	Severely disabled; hospital admission is indicated although death not imminent.

20	Very sick; hospital admission necessary; active supportive treatment necessary.
10	Moribund; fatal processes progressing rapidly.
0	Dead

ECOG (select a response) :

	Score					
	0	**1**	**2**	**3**	**4**	**5**
	ECOG Performance Status*					
*As published in Am. J. Clin. Oncol.: Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982	Fully active	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	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair	Dead

M2 CDA: Bone Mets Baseline Medication Reconciliation Form

Time points: Pre-Treatment

Data Elements	Options
What is the treatment start date (RT start date) associated with this form?	_____ (mm/dd/yyyy)
List the current opioid medication(s) the patient was prescribed. • Medication Name • Dose • Frequency	_____ (name) _____ (dose) _____ (frequency)
Check if the patient is not currently taking opioid medication	• Check box

M3 CDA: Bone Mets Systemic Therapy Data

Time points: Pre-Treatment

Data Elements	Options

What is the treatment start date (RT start date) associated with this form?	_____ (mm/dd/yyyy)
Did the patient receive systemic therapy in the four weeks prior to the start of RT?	• Yes • No
If Yes, was the systemic therapy:	• Chemotherapy • Immunotherapy • Targeted therapy • Endocrine/ hormonal therapy
Is the patient taking any systemic therapy concurrently with radiotherapy?	• Yes • No
If Yes, was the systemic therapy:	• Chemotherapy • Immunotherapy • Targeted therapy • Endocrine/ hormonal therapy

M4 Physician: Bone Mets Toxicity Evaluation

Time points: Pre-Treatment

Data Elements	**Options**
What is the treatment start date (RT start date) associated with this form?	_____ (mm/dd/yyyy)
Total number of all metastatic lesions—not just bone:	• 1-2 • 3-5 • > 5-10 • > 10
In addition to bone, is there metastatic disease in the CNS or viscera? ➢ If yes, please specify where:*(check all that apply)*	• Yes/No • Adrenal Glands • Brain • Liver

	• Lung • Lymph Nodes • Other, please specify where: _____
Number of distinct bony regions being treated:	_____ (free text)

For each distinct bony region, list location of bony regions being treated.

Site 1	□ Femur □ Hip □ Humerus □ Pelvis □ Rib/Sternum □ Shoulder/Scapula □ Skull □ Spine – select levels to be treated (select all that apply): □ Cervical □ Thoracic □ Lumbar □ Sacral □ Other:_____	Is there an associated soft tissue mass? ❑ Yes ❑ No
Site 2	□ Femur □ Hip □ Humerus □ Pelvis □ Rib/Sternum □ Shoulder/Scapula □ Skull □ Spine – select levels to be treated (select all that apply): □ Cervical □ Thoracic □ Lumbar □ Sacral □ Other:_____	Is there an associated soft tissue mass? ❑ Yes ❑ No
Site 3	□ Femur □ Hip □ Humerus □ Pelvis □ Rib/Sternum □ Shoulder/Scapula □ Skull □ Spine – select levels to be treated (select all that apply): □ Cervical □ Thoracic □ Lumbar □ Sacral □ Other:_____	Is there an associated soft tissue mass? ❑ Yes ❑ No
Site 4	□ Femur □ Hip □ Humerus □ Pelvis □ Rib/Sternum □ Shoulder/Scapula □ Skull □ Spine – select levels to be treated (select all that apply): □ Cervical □ Thoracic □ Lumbar □ Sacral □ Other:_____	Is there an associated soft tissue mass? ❑ Yes ❑ No

Site 5	□ Femur □ Hip □ Humerus □ Pelvis □ Rib/Sternum □ Shoulder/Scapula □ Skull □ Spine – select levels to be treated (select all that apply): □ Cervical □ Thoracic □ Lumbar □ Sacral □ Other:_____	Is there an associated soft tissue mass? ❑ Yes ❑ No

Primary intent of this course of treatment?	• Palliation of pain • Durable local control to prevent later problem (e.g., prevention of pathologic fracture, spine metastasis to prevent later cord compression, etc.) • Treatment of existing pathological fracture (i.e., post-fracture or post-operatively) • Treatment of spinal cord compression • Curative intent or improvements in progression-free survival (e.g., oligometastasis treatment)
Is this patient part of a prospective clinical protocol or registry study (do not include MROQC)?	• Yes • No
Does this study (these studies) influence your radiation dose/treatment plan, or expected toxicity for this patient?	• not applicable/not on study • Yes • No
Is the patient scheduled to receive systemic therapy after radiotherapy?	• Yes • No
➢ A) If yes, does this influence your radiation dose/treatment plan for this patient?	• Yes • No
➢ B) If yes, is the systemic therapy:	• Chemotherapy • Immunotherapy • Targeted therapy • Endocrine/ hormonal therapy

MICHIGAN RADIATION ONCOLOGY QUALITY CONSORTIUM

MROQC Bone Mets Data Elements Guide

Symptom Scoring

	Grade					
	n/a	**1**	**2**	**3**	**4**	**5**
Gastrointestinal disorders						
Esophagitis		Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered eating/swallowing; oral supplements indicated	Severely altered eating/swallowing; tube feeding, TPN or hospitalization indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Diarrhea		Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline	Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline	Increase of >=7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL	Life-threatening consequences; urgent intervention indicated	Death
Nausea		Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition	Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated		
Vomiting		1 - 2 episodes (separated by 5 minutes) in 24 hrs.	3 - 5 episodes (separated by 5 minutes) in 24 hrs.	>=6 episodes (separated by 5 minutes) in 24 hrs.; tube feeding, TPN or hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Fatigue						
Fatigue		Fatigue relieved by rest	Fatigue not relieved by rest; limiting instrumental ADL*	Fatigue not relieved by rest; limiting self-care ADL*		
Renal and Urinary Disorders						
Urinary Frequency		Present	Limiting instrumental ADL; medical management indicated			
Urinary Urgency		Present	Limiting instrumental ADL; medical management indicated			
Skin						
Dermatitis		Faint erythema or dry desquamation	Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema	Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion	Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated	Death

M5 CDA: Bone Mets Follow-up

Time points: Complete 6-weeks post-RT end date

Data Elements	Options
What is the treatment start date (RT start date) associated with this form?	_____ (mm/dd/yyyy)

Weight	• _____ (specify lbs. or kg) • not documented
Was there clinical or local progression at the treated site?	• Yes • No
Was additional cancer therapy given after palliative RT? ➢ If yes: ➢ If systemic:	• Yes • No • Surgery • Systemic • Chemotherapy • Immunotherapy • Targeted therapy • Endocrine/ hormonal therapy
Was additional RT given? ➢ If yes	• Yes • No • Same area • Different
Has the patient been enrolled in hospice since the end of RT	• Yes • No

Karnofsky Performance Scale (circle response)	
100	Normal no complaints; no evidence of disease.
90	Able to carry on normal activity; minor signs or symptoms of disease.
80	Normal activity with effort; some signs or symptoms of disease.
70	Cares for self; unable to carry on normal activity or to do active work.

60	Requires occasional assistance, but is able to care for most of his personal needs.
50	Requires considerable assistance and frequent medical care.
40	Disabled; requires special care and assistance.
30	Severely disabled; hospital admission is indicated although death not imminent.
20	Very sick; hospital admission necessary; active supportive treatment necessary.
10	Moribund; fatal processes progressing rapidly.
0	Dead

Toxicity Scoring (CTCAE v 4.0)

	Grade					
	n/a	**1**	**2**	**3**	**4**	**5**
Gastrointestinal disorders						
Esophagitis		Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered eating/swallowing; oral supplements indicated	Severely altered eating/swallowing; tube feeding, TPN or hospitalization indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Diarrhea		Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline	Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline	Increase of >=7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL	Life-threatening consequences; urgent intervention indicated	Death
Nausea		Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition	Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated		
Vomiting		1 - 2 episodes (separated by 5 minutes) in 24 hrs.	3 - 5 episodes (separated by 5 minutes) in 24 hrs.	>=6 episodes (separated by 5 minutes) in 24 hrs.; tube feeding, TPN or hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Fatigue						
Fatigue		Fatigue relieved by rest	Fatigue not relieved by rest; limiting instrumental ADL*	Fatigue not relieved by rest; limiting self-care ADL*		
Renal and Urinary Disorders						
Urinary Frequency		Present	Limiting instrumental ADL; medical management indicated			

Urinary Urgency		Present	Limiting instrumental ADL; medical management indicated			
Skin						
Dermatitis		Faint erythema or dry desquamation	Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema	Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion	Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated	Death

Was medication prescribed for any radiation treatment related toxicity? ➢ If yes, note toxicity and medication:	• Yes • No _____ (free text)
Was a clinical procedure performed due to radiation treatment related toxicity? ➢ If yes, note toxicity and procedure:	• Yes • No _____ (free text)
Since completing treatment, has the patient been hospitalized or seen in the ED for radiation treatment related toxicity? ➢ If yes: ➢ If yes, note toxicity:	• Yes • No • ED • Hospitalization _____ (free text)

M6 Patient: Pre-Treatment Bone Mets Questionnaire	
	Time points: Pre-Treatment
Data Elements	**Options**
What is the treatment start date (RT start date) associated with this form?	_____ (mm/dd/yyyy)
Do you have any trouble taking a short walk outside of the house? Do you need to stay in bed or a chair during the day? Do you need help with eating, dressing, washing yourself or using the toilet? Were you short of breath? Have you had pain? I feel ill Have you had trouble sleeping? Have you felt weak? Have you lacked appetite? Have you felt nauseated? Have you been constipated? Were you tired? Did pain interfere with your daily activities? Did you feel tense? Did you feel depressed?	• Not at all • A little • Quite a bit • Very much • Not at all • A little • Quite a bit • Very much
How would you rate your overall quality of life during the last 3 days?	_____ Scale (0-10)

Rate your pain at its worst at your treated site(s) within the last 3 days.	_____ Scale (0-10)
Have you ever, even once, used Cannabis?	• Prefer not to answer • No • Yes
Think specifically about the past 30 days up to and including today. What is your best estimate of the number of days you used Cannabis during the past 30 days?	• 0 days • 1 or 2 days • 3 to 5 days • 6 to 9 days • 10 to 19 days • 20 to 29 days • All 30 days
What is the highest level of education you have completed?	• Grade School or less • Some College or Technical School • Some High School • Associate's Degree • High School Graduate or G.E.D. • College Graduate (Bachelor's Degree) • Graduate Degree
Which of the following best describes your race?	• American Indian/Alaska Native • Asian • Native Hawaiian or other Pacific Islander • Black or African American • White • Arab/Middle Eastern • Other (please specify) _____
During the past 30 days, which one of the following ways did you use cannabis most often? Did you usually:	• Smoke it (for example, in a joint, bong, pipe, or blunt) • Eat it (for example, in brownies, cakes, cookies, or candy) • Drink it (for example, in tea, cola, or alcohol) • Vaporize it (for example, in an e-cigarette-like vaporizer or another vaporizing device) • Dab it (for example, using waxes or concentrates) • Apply to skin (for example, using lotions or oils) • Administer rectally (for example, using suppositories).

	• Use it some other way (please specify: _____)
What is the major active ingredient in the cannabis product that you use the most? (This information can often be found on the package label.)	• THC –also called tetrahydrocannabinol • CBD –also called cannabidiol • Balanced levels of THC and CBD • I don't know

M7 Patient: 6-week Follow-up Survey

Time points: Complete 6-weeks post-RT end date

Data Elements	Options
What is the treatment start date (RT start date) associated with this form?	_____ (mm/dd/yyyy)
Do you have any trouble taking a short walk outside of the house?	• Not at all • A little • Quite a bit • Very much
Do you need to stay in bed or a chair during the day?	
Do you need help with eating, dressing, washing yourself or using the toilet?	
Were you short of breath?	
Have you had pain?	
I feel ill	
Have you had trouble sleeping?	
Have you felt weak?	
Have you lacked appetite?	• Not at all • A little • Quite a bit • Very much
Have you felt nauseated?	
Have you been constipated?	
Were you tired?	
Did pain interfere with your daily activities?	

Did you feel tense? Did you feel depressed?	
How would you rate your overall quality of life during the past week?	_____ Scale (0-7)
How would you rate your overall quality of life during the last 3 days?	_____ Scale (0-10)
Rate your pain at its worst at your treated site(s) within the last 3 days?	_____ Scale (0-10)
Thinking about your level of pain before starting treatment, did you experience an increase in pain after beginning treatment and up to 1 week following the end of treatment?	• Yes • No
Were you prescribed medication to treat side effects related to your radiation treatment?	• Yes • No
Were you prescribed steroids during treatment?	• Yes • No
Have you been seen in the ED or hospitalized since completing radiation treatment? ➢ If yes, how many times for the ED for Hospital?	• Yes • No • ED_____ (free text) • Hospital_____ (free text)
Was radiation related side effects the reason for your emergency room visit or hospitalization?	• Yes • No • N/A

➢ If yes, how many times?	_____ (free text)
Was pain a reason for your ED visit or hospitalization? ➢ If yes, how many times?	• Yes • No • N/A _____ (free text)

M8 CDA: Bone Mets Follow-up Medication Reconciliation Form	
Time points: Complete 6-weeks post-RT end date	
Data Elements	**Options**
What is the treatment start date (RT start date) associated with this form?	_____(mm/dd/yyyy)
List the current opioid medication(s) the patient was prescribed. • Medication Name • Dose • Frequency Check if the patient is not currently taking opioid medication	 _____ (name) _____ (dose) _____ (frequency) • Check box

SE2 CDA: Early Termination of MROQC Patient Participation Form	
Data Elements	**Options**
What is the treatment start date (RT start date) associated with this form?	_____(mm/dd/yyyy)
Date of Early Termination:	_____If the patient died this would be the date of death otherwise it is the last eval. date the patient had

Reason patient is no longer being followed /participating in MROQC:	• Moved • To continue treatment elsewhere • Deceased • Hospice • Patient chose to stop treatment • Patient chose to not follow-up with department • Medical issues (i.e. CVA, MI) prevent further participation

BONE METS Radiotherapy Technical Details Form	
Data Elements	**Options**
What is the treatment start date (RT start date) associated with this form?	_____(mm/dd/yyyy)
Select the planning type used for this plan:	• Forward planning • Inverse planning • Hybrid technique (forward and inverse planning)
What delivery technique(s) were used in this plan?	• 2D • 3D • IMRT • Hybrid (3D and IMRT)
Was this plan considered SBRT?	• Yes • No
Were standardized dose constraints used for organs at risk (OARs)?	• Yes • No
If any constraints were violated, was the rationale for their violation documented?	• Yes • No • Not applicable – no constraint violations

How was this plan billed?	• 2D • 3D • IMRT • SBRT *Note: DICOM data upload is required for plans billed as IMRT or SBRT.*
Was a simultaneous integrated boost included in this plan?	• Yes • No
Select the number of targets treated by this plan:	• drop-down menu: 1-3
TARGETS For each target, specify: ➢ a. Enter the name of this target:	_____ free text
➢ b. Choose all treatment sites included in this target:	• Femur • Shoulder/Scapula • Hip • Skull • Humerus • Spine – select all levels treated: Cervical, Thoracic, Lumbar, Sacral • Pelvis • Other. Please specify: _____ • Rib/Sternum
➢ c. Was a GTV structure contoured?	• Yes • No

➢ d. Was a CTV structure contoured?	• Yes • No
➢ e. What is the approximate margin between the GTV structure and CTV structure in cm? _____cm	• if Q6c = "Yes" and Q6d = "Yes" [between 0 and 5]
➢ f. Was a PTV structure contoured?	• Yes • No
➢ g. What is the approximate margin between the CTV structure (or GTV structure if CTV structure was not defined) and PTV structure in cm? _____ cm	• if Q6f = "Yes" and Q6c or Q6d = "Yes" [between 0 and 5]
➢ h. Dose delivered to this target (Gy):	_____ [between 1 and 50]
➢ i. Number of fractions delivered to this target:	_____ [between 1 and 25]
➢ j. Did the target receive all of the planned dose?	• Yes • No
➢ k. Was there any previous radiotherapy to the same target?	• Yes, to the entire target • Yes, some overlap with target • No
Image Guidance What type of imaging was used to verify this patient's setup?	• kV/MV portal • CT (CBCT or TomoTherapy CT) • Other. Please specify: _____

For each imaging type, specify how often the patient was imaged during treatment.	• Daily • Less than daily but more than weekly • Weekly • Other. Please specify: