The PCWG2 Bone Scan Form Guidelines Alliance #A031201

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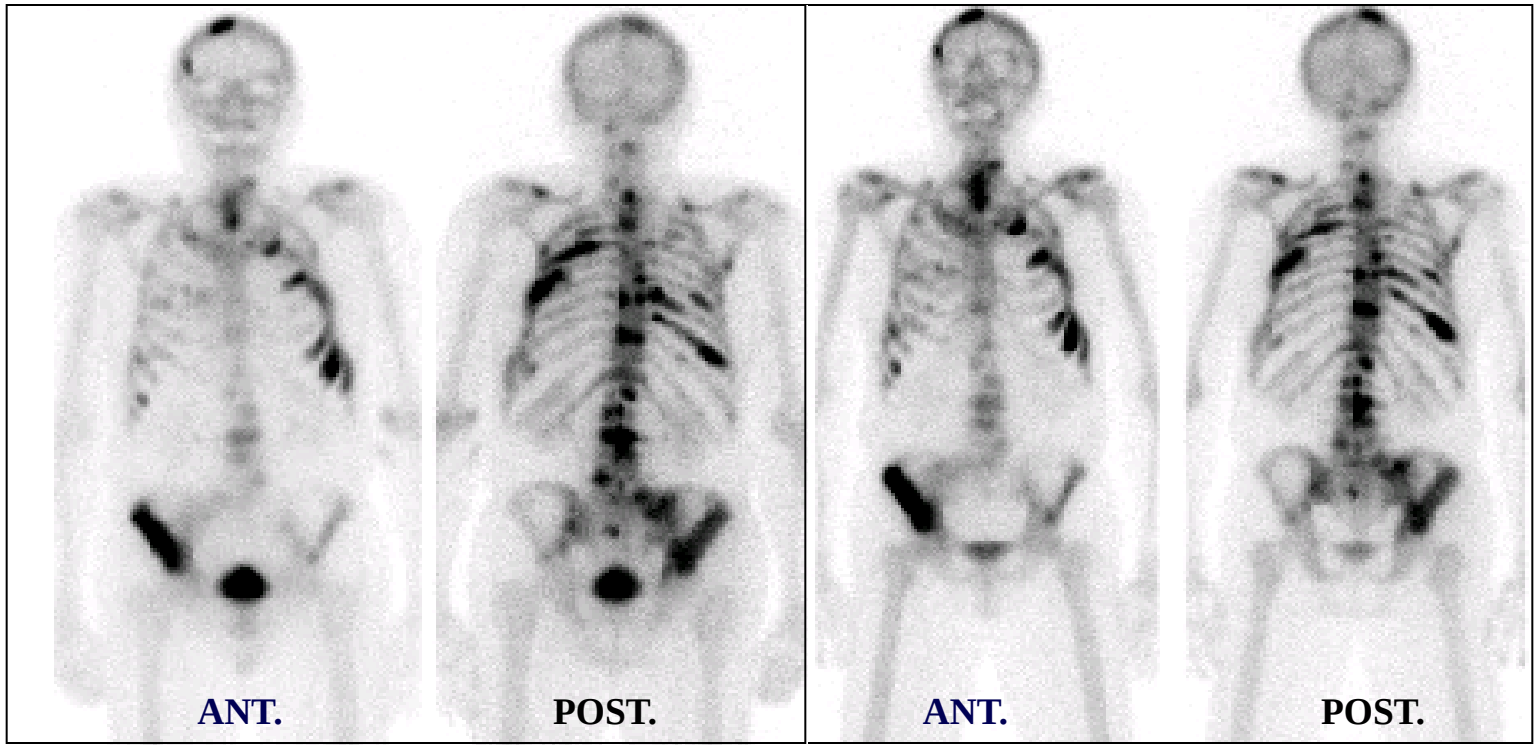
Prostate Cancer and Imaging

- The disease is bone-tropic and lesions are not measurable
- RECIST was developed without using prostate cancer patients
- Imaging is often mis-leading, and sometimes you would have been better off not taking pictures at all

Standard Bone Scans: Poorly Reflect Anti-Tumor Effects

Failure to Reflect Response



Baseline **After 3 months of treatment**

PSA= 75 ng/ml **PSA=8.6 ng/ml**

Courtesy Steve Larson

Baseline
PSA= 2.6

3 months of treatment
PSA=0.52 ng/ml
New lesions=POD by RECIST

4 months of treatment
PSA=0.35 ng/ml

18 months of treatment
PSA=0.52 ng/ml

Changes in PSA levels in CRPC patients treated with abiraterone acetate plus prednisone.

- Flare on bone scan
  - 30% (10/33 patients) of enrolled patients
  - 43.5% (10/23 patients) of PSA responders

Ryan C J et al. Clin Cancer Res 2011;17:4854-4861

The Need for an Imaging Biomarker: PCWG2

Design and End Points of Clinical Trials for Patients With Progressive Prostate Cancer and Castrate Levels of Testosterone: Recommendations of the Prostate Cancer Clinical Trials Working Group

Howard I. Scher, Susan Halabi, Ian Tannock, Michael Morris, Cora N. Sternberg, Michael A. Carducci, Mario A. Eisenberger, Celestia Higano, Glenn J. Bubley, Robert Dreicer, Daniel Petrylak, Philip Kantoff, Ethan Basch, William Kevin Kelly, William D. Figg, Eric J. Small, Tomasz M. Beer, George Wilding, Alison Martin, and Maha Hussain

JCO 2008

- Recommendation that radiographic PFS be emphasized rather than PSA as an endpoint

- Criteria proposed for defining POD by bone scans and controlling for flare

The PCWG Proposed Criteria to Standardize the Assessment of Bone Disease

No definition for response provided

Progression:

> 1 new lesion

Worsening scan = progressive disease, regardless of PSA

For control/relieve eliminate end points:

Record outcome as new lesions or no new lesions

First scheduled reassessment:

No new lesions: continue therapy

New lesions: perform a confirmatory scan 6 or more weeks later

Confirmatory scan:

No new lesions: continue therapy

Additional new lesions: progression

Subsequent scheduled reassessments:

No new lesions: continue

New lesions: progression

For prevent/delay end points (progression):

The appearance of ≥ 2 new lesions, and, for the first reassessment only, a confirmatory scan performed 6 or more weeks later that shows a minimum of 2 or more additional new lesions§

The date of progression is the date of the first scan that shows the change

Scher et al., PCWG2, JCO, 2008

Impact of PCWG2 on Trial Design

- Scans rather than PSA determines how long patients stay on study

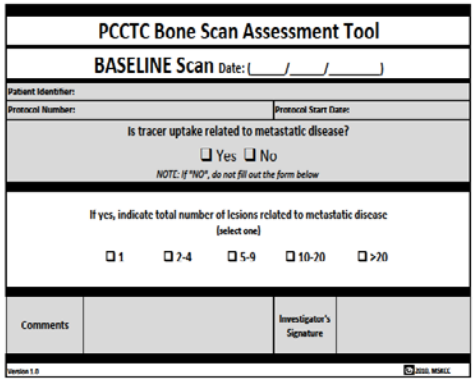
- Time to progression (or duration of effect) be emphasized in determining the promotion or abandonment of drugs from phase II to III

Definition of POD: The basics
Count to two!!!

- To control for flare:
  - Nobody comes off treatment for new disease on the first post-treatment scan (week 9)
  - You only come off treatment if you have ≥2 new lesions on the first post-treatment scan *and* you have ≥2 new lesions on the subsequent (week 17 scan)
  - This is the “2+2” rule

- Progression otherwise:
  - 2 new *confirmed* lesions using the week 9 scan as the baseline

Development of Prostate Cancer Clinical Trials Consortium Bone Scan Data Capture Forms: The bone scan “assay”



PCCTC Bone Scan Assessment Tool

BASELINE Scan Date: (____/____/_____)

Patient Identifier:

Protocol Number: | Protocol Start Date:

Is tracer uptake related to metastatic disease?

❑ Yes ❑ No

NOTE: If "NO", do not fill out the form below

If yes, indicate total number of lesions related to metastatic disease (select one)

❑ 1 ❑ 2-4 ❑ 5-9 ❑ 10-20 ❑ >20

Comments | Investigator's Signature

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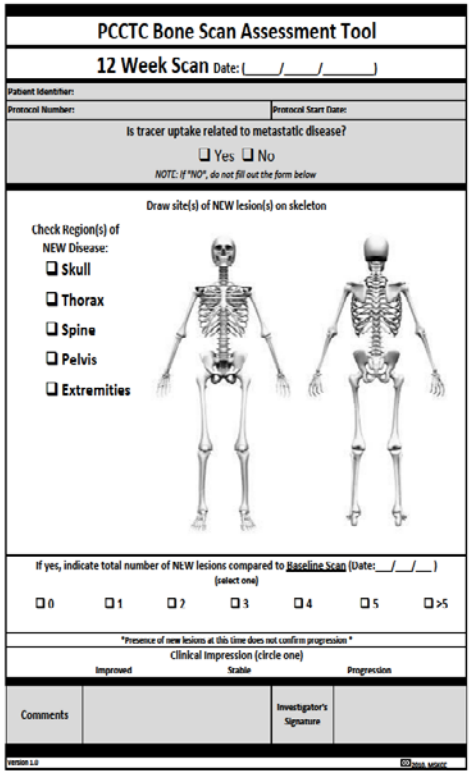

PCCTC Bone Scan Assessment Tool

12 Week Scan Date: (____/____/_____)

Patient Identifier:

Protocol Number: | Protocol Start Date:

Is tracer uptake related to metastatic disease?

❑ Yes ❑ No

NOTE: If "NO", do not fill out the form below

Draw site(s) of NEW lesion(s) on skeleton

Check Region(s) of NEW Disease:

❑ Skull

❑ Thorax

❑ Spine

❑ Pelvis

❑ Extremities

If yes, indicate total number of NEW lesions compared to Baseline Scan (Date: __/__/___) (select one)

❑ 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ >5

*Presence of new lesions at this time does not confirm progression *

Clinical Impression (circle one)

Improved Stable Progression

Comments | Investigator's Signature

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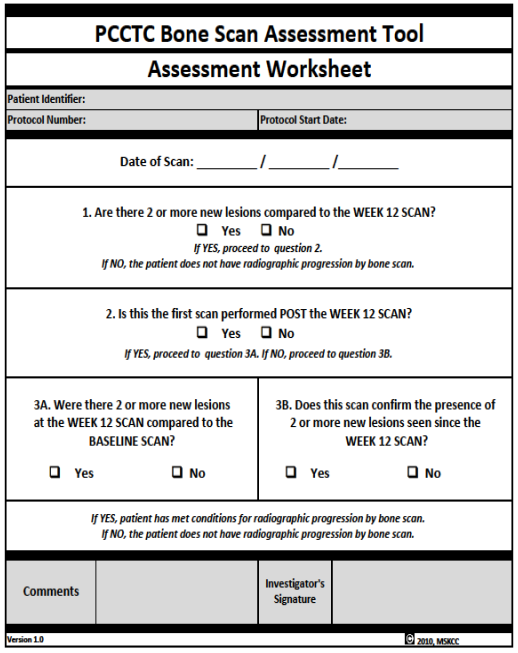

PCCTC Bone Scan Assessment Tool

Assessment Worksheet

Patient Identifier:

Protocol Number: | Protocol Start Date:

Date of Scan: _____/_____/_____

1. Are there 2 or more new lesions compared to the WEEK 12 SCAN?

❑ Yes ❑ No

If YES, proceed to question 2.

If NO, the patient does not have radiographic progression by bone scan.

2. Is this the first scan performed POST the WEEK 12 SCAN?

❑ Yes ❑ No

If YES, proceed to question 3A. If NO, proceed to question 3B.

3A. Were there 2 or more new lesions at the WEEK 12 SCAN compared to the BASELINE SCAN?

❑ Yes ❑ No

3B. Does this scan confirm the presence of 2 or more new lesions seen since the WEEK 12 SCAN?

❑ Yes ❑ No

If YES, patient has met conditions for radiographic progression by bone scan.

If NO, the patient does not have radiographic progression by bone scan.

Comments | Investigator's Signature

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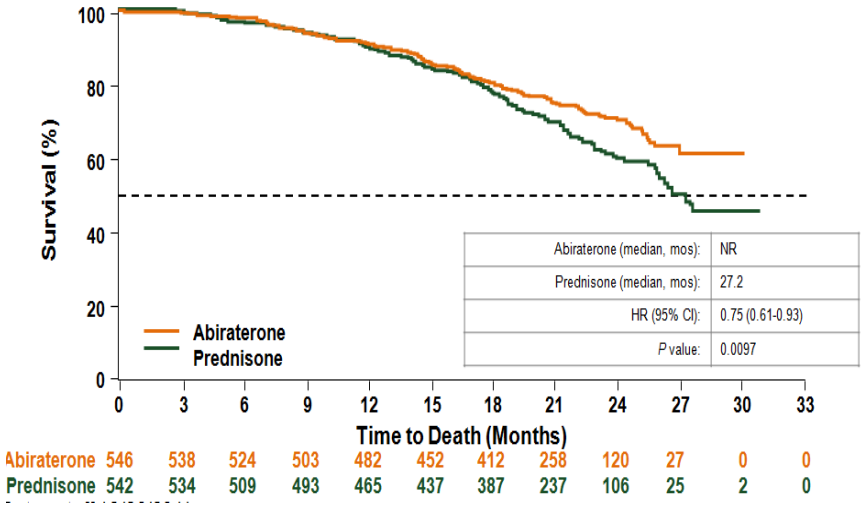
PCWG2 qualification: multiple phase III placebo-controlled trials with OS endpoints

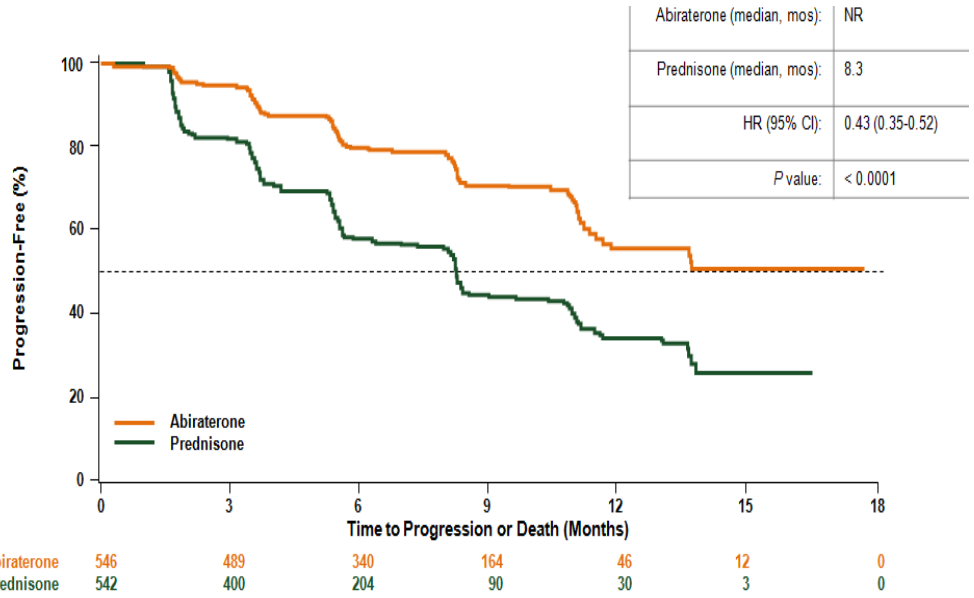
- “Cou302”: Abiraterone/prednisone vs. placebo/prednisone
  - rPFS and OS positive
- PREVAIL: Enzalutamide vs. placebo
  - rPFS and OS positive
- ELM-PC4: Orteronel/prednisone vs. placebo/prednisone
  - rPFS positive and OS negative

Abiraterone/prednisone vs. Placebo/prednisone



OS

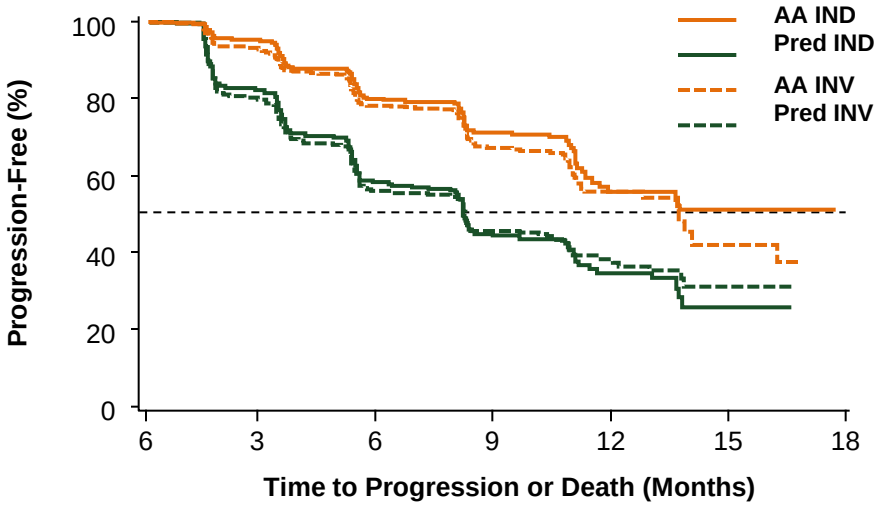
rPFS



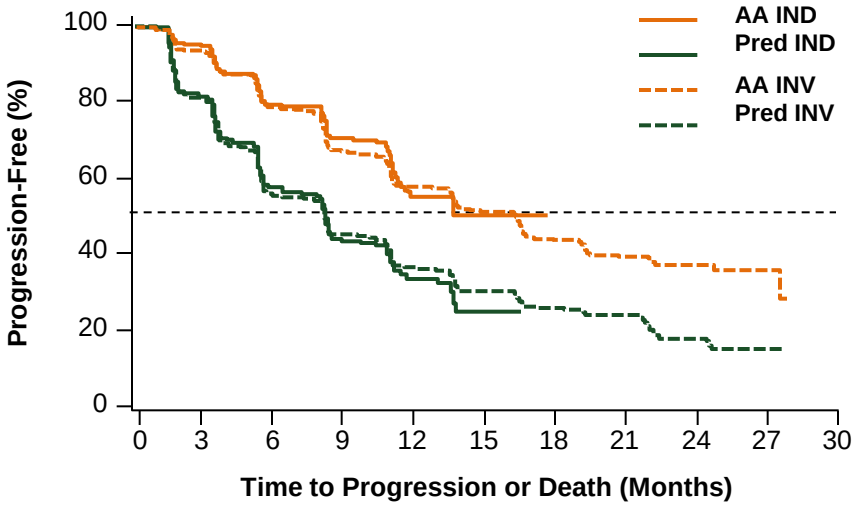
Ryan NEJM 2013

rPFS Was Highly Consistent Between Independent and Investigator Reviews

IND 2010 – INV 2010



IND 2010 – INV 2011



- **Agreement between independent and investigator assessment on rPFS event status was observed (abiraterone group, 430/546 [79%]; prednisone group, 414/542 [76%])***

*based on the IND 2010 – INV 2010 analysis.

IND, independent review; INV, investigator review

Ryan NEJM 2013

Positive Association of rPFS With OS

Association of rPFS and OS at Dec 2011 Interim Analysis*	
0.72	
Spearman Rho (r)	**Level of Association**
-1	Negatively associated
0	No association
1	Positively associated

*Per Spearman's correlation coefficient estimated through Clayton copula.

Ryan NEJM 2013

PCWG2 Guidelines

Selecting Lesions

- The reviewers are to use their best clinical judgment to ensure that only unequivocal lesions related to prostate cancer are recorded on the eCRF at any time point.
- At follow-up time points only new lesions are to be recorded.

Lesion Assessment

- Changes in intensity are not to be taken into consideration when assessing bone scan lesions.
- Previously identified new lesions thought to be flare at a later visit should be assessed as absent and comments entered on the form.

PCWG2 Guidelines

Missed New lesion

- If a new lesion is overlooked, and not identified until a later time point, record the lesion at the current time point with a comment. Record the date that the lesion could reasonably first be identified.

PCWG2 Guidelines

Missing Anatomy

- Always indicate missing anatomy as an image quality issue.
- If anatomy is missing at baseline and a follow-up visit includes the missing anatomy with lesions, these lesions will not be recorded as new. The overall response for the visit should be Unknown, unless PD can be assessed elsewhere.
- If anatomy is missing at baseline and a follow-up visit includes the missing anatomy with no lesions present all assessment options are valid.
- If anatomy is consistently missing at all time points all assessment options are valid.

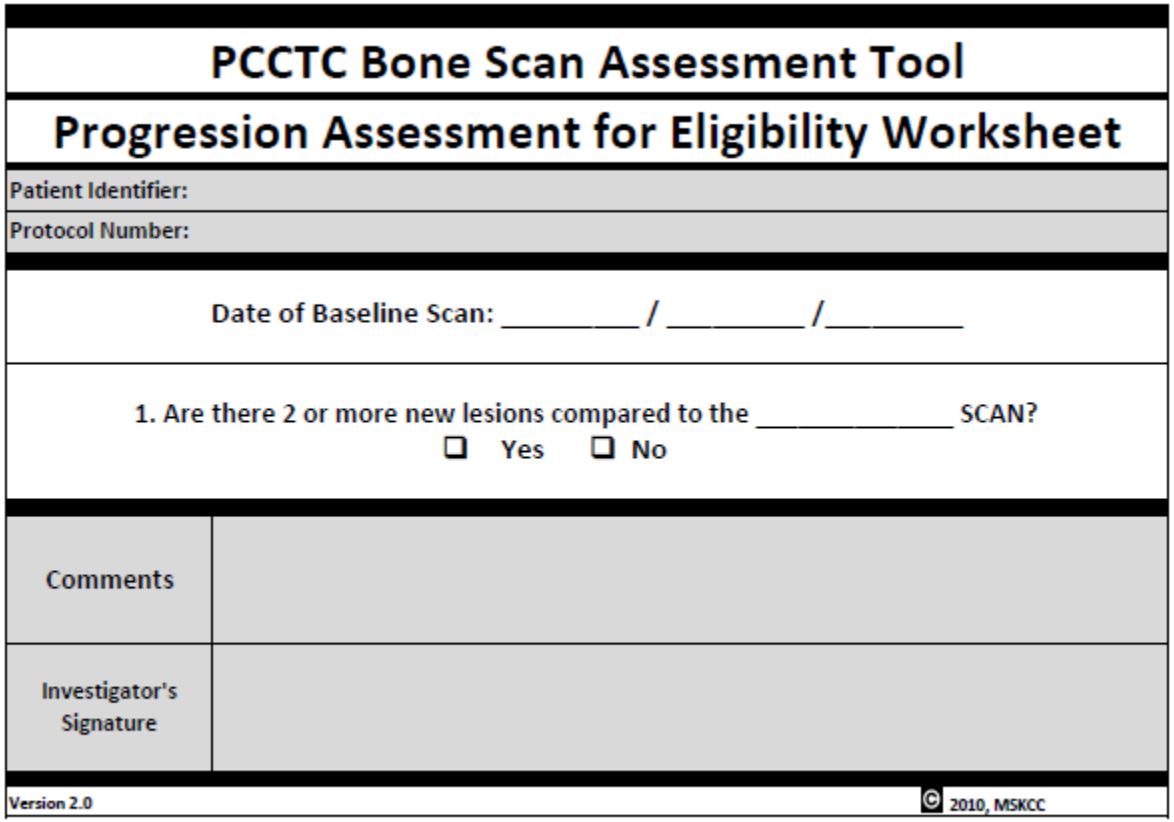
PCWG2 Guidelines

Disease progression on bone scan under PCWG2 is defined as:

Date Progression Detected	Criteria for Progression	Criteria for Confirmation or Progression (requirement and timing)	Criteria for Documentation of Disease Progression on Subsequent Scan
Week 9	Two or more new lesions compared to baseline bone scan.	Timing: at least 6 weeks after progression identified or at Week 17	Two or more new bone lesions on the week 17 bone scan (compared to Week 9 scan)
Week 17	Two or more new lesions on bone scan compared to Week 9 bone scan.	Timing: at least 6 weeks after progression identified or at Week 25 Visit.	Persistent or increase in number of bone lesions on any subsequent bone scan compared to Week 17 scan.
Week 25 or later	Two or more new lesions on bone scan compared to Week 9 bone scan.	Timing: at least 6 weeks after progression identified.	Persistent or increase in number of lesions on bone scan compared to prior scan.

Note: 2 or more lesions that have fused (become 1) since prior assessment should continue to be counted as original number. A single lesion that has split (divided) since prior assessment should still be counted as one lesion.

Eligibility Worksheet



PCCTC Bone Scan Assessment Tool

Progression Assessment for Eligibility Worksheet

Patient Identifier:

Protocol Number:

Date of Baseline Scan: _____ / _____ /_____

1. Are there 2 or more new lesions compared to the _____ SCAN?

☐ Yes ☐ No

Comments	
Investigator's Signature	

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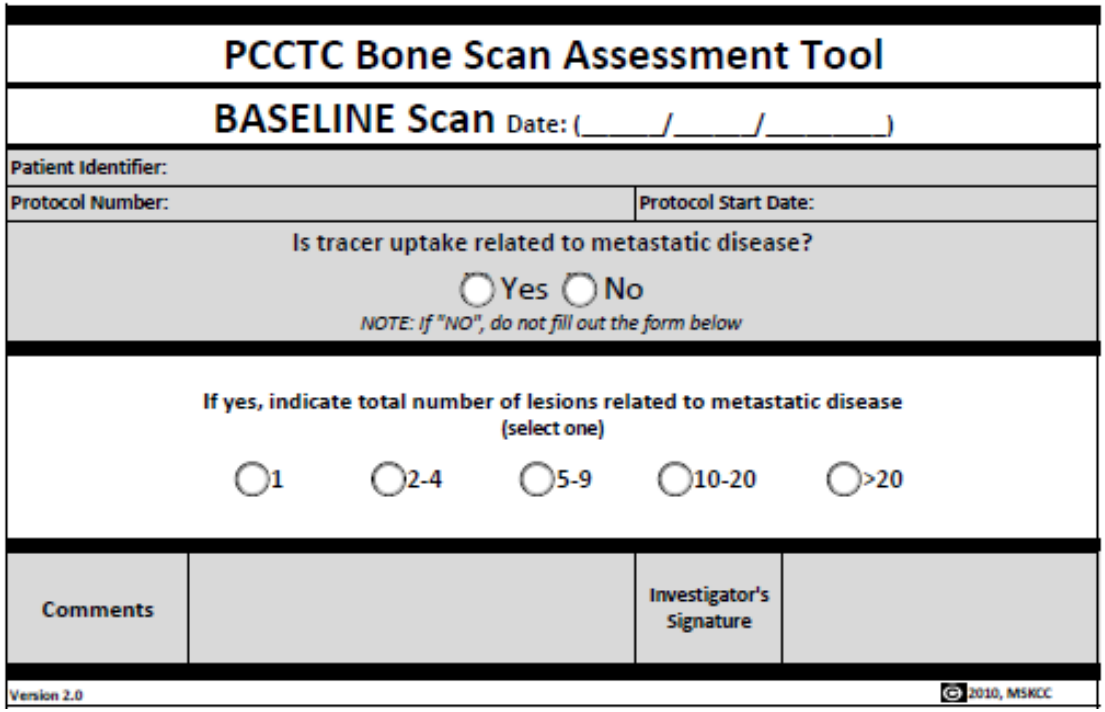
Eligibility Worksheet

- Patient must have bone disease progression defined by two or more new lesions on the baseline bone scan compared to a previous scan date

Baseline Bone Scan



PCCTC Bone Scan Assessment Tool

BASELINE Scan Date: (_____/_____/_____)

Patient Identifier:	
Protocol Number:	Protocol Start Date:

Is tracer uptake related to metastatic disease?

◯ Yes ◯ No

NOTE: If "NO", do not fill out the form below

If yes, indicate total number of lesions related to metastatic disease (select one)

◯ 1 ◯ 2-4 ◯ 5-9 ◯ 10-20 ◯ >20

Comments		Investigator's Signature	

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Baseline Bone Scan

- Must be within 28 days prior to patients start of treatment

9 Week Bone Scan

PCCTC Bone Scan Assessment Tool

9 Week Scan Date: (_____/_____/_____)

Patient Identifier:	
Protocol Number:	Protocol Start Date:

Is tracer uptake related to metastatic disease?

◯ Yes ◯ No

NOTE: If "NO", do not fill out the form below

Draw site(s) of NEW lesion(s) on skeleton

Check Region(s) of NEW Disease:

- ☐ Skull
- ☐ Thorax
- ☐ Spine
- ☐ Pelvis
- ☐ Extremities

If yes, indicate total number of NEW lesions compared to Baseline Scan (Date:___/___/___)

(select one)

◯0 ◯1 ◯2 ◯3 ◯4 ◯5 ◯>5

*Presence of new lesions at this time does not confirm progression *

Clinical Impression (circle one)

◯ Improved ◯ Stable ◯ Progression

Comments		Investigator's Signature	

Version 2.0

Follow-Up Bone Scan (Post-9Wk)

PCCTC Bone Scan Assessment Tool

_____ **Week Scan** Date: (_____/_____/_____)

****To be compared to 9 Week Scan****

Patient Identifier:	
Protocol Number:	Protocol Start Date:

Is tracer uptake related to metastatic disease?

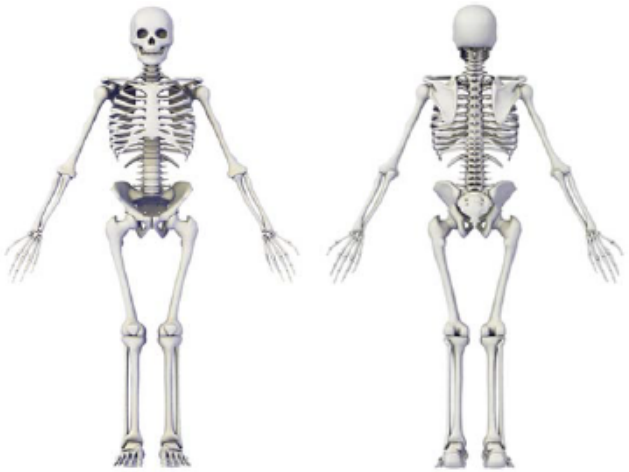
◯ Yes ◯ No

NOTE: If "NO", do not fill out the form below

Draw site(s) of NEW lesion(s) on skeleton

Check Region(s) of NEW Disease:

- ☐ Skull
- ☐ Thorax
- ☐ Spine
- ☐ Pelvis
- ☐ Extremitie



If yes, indicate total number of NEW lesions compared to 9 Week Scan (Date:___/___/___)

(select one)

◯0 ◯1 ◯2 ◯3 ◯4 ◯5 ◯>5

Clinical Impression (circle one)

◯ Improved ◯ Stable ◯ Progression

Comments		Investigator's Signature	

Version 2.0

Progression Form (post Week 9)

PCCTC Bone Scan Assessment Tool

Progression Assessment Worksheet

Patient Identifier:	
Protocol Number:	Protocol Start Date:

Date of Scan: _____ / _____ /_____

1. Are there 2 or more new lesions compared to the WEEK 9 SCAN?

◯ Yes ◯ No

If YES, proceed to question 2.
If NO, the patient does not have radiographic progression by bone scan.

2. Is this the first scan performed POST the WEEK 9 SCAN?

◯ Yes ◯ No

If YES, proceed to question 3A. If NO, proceed to question 3B.

3A. Were there 2 or more new lesions at the WEEK 9 SCAN compared to the BASELINE SCAN?	3B. Does this scan confirm the presence of 2 or more new lesions seen since the WEEK 9 SCAN?
◯ Yes ◯ No	◯ Yes ◯ No

If YES, patient has met conditions for radiographic progression by bone scan.
If NO, the patient does not have radiographic progression by bone scan.

Comments		Investigator's Signature	

Version 2.0

Progression Scenarios

Progression of Disease (POD) by Bone

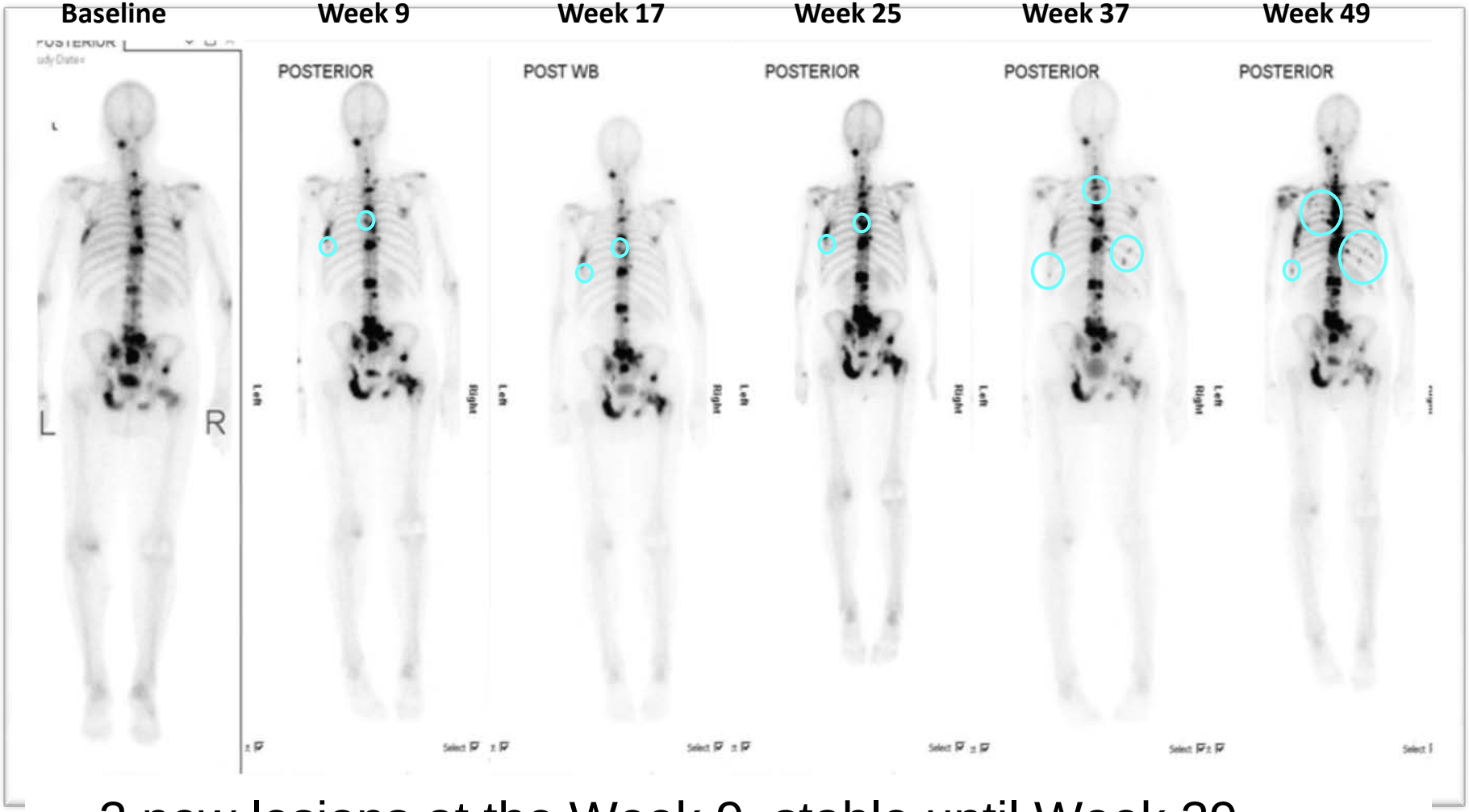
KEY:
- = Date of Progression
- = Confirmatory Scan
- = Original Bone Lesions
- = New Bone Lesions (colored)

Case#	BL(0wk)	FU1(9 wk)	FU2(17 wk)	FU3(25 wk)	FU4(37 wk)	Comments
# 1	no lesions	no new lesions				**POD at FU3, confirmed at FU4.** Two new lesions are seen at FU3 compared to the first assessment (FU1). These are confirmed at FU4.
# 2						**POD at FU3, confirmed at FU4.** Two new lesions are seen at FU3 compared to FU1. These are confirmed at FU4.
# 3						**POD at FU3, confirmed at FU4.** Two new lesions are seen at FU1, but there is only one additional new lesions at FU2. Therefore, the two new lesions see at FU1 are considered flare by definition, and thus it is not POD yet. At FU3, there are two new lesions compared to FU1, which are confirmed at FU4.
# 4						**POD at FU1, confirmed at FU2.** Two new lesions exist at FU1, and FU2 shows two additional new lesions, thereby fullfilling POD definition.
# 5						**No POD.** There are not two new lesions compared to FU1.

Scenario 1: Early BS Flare
Slow Progression

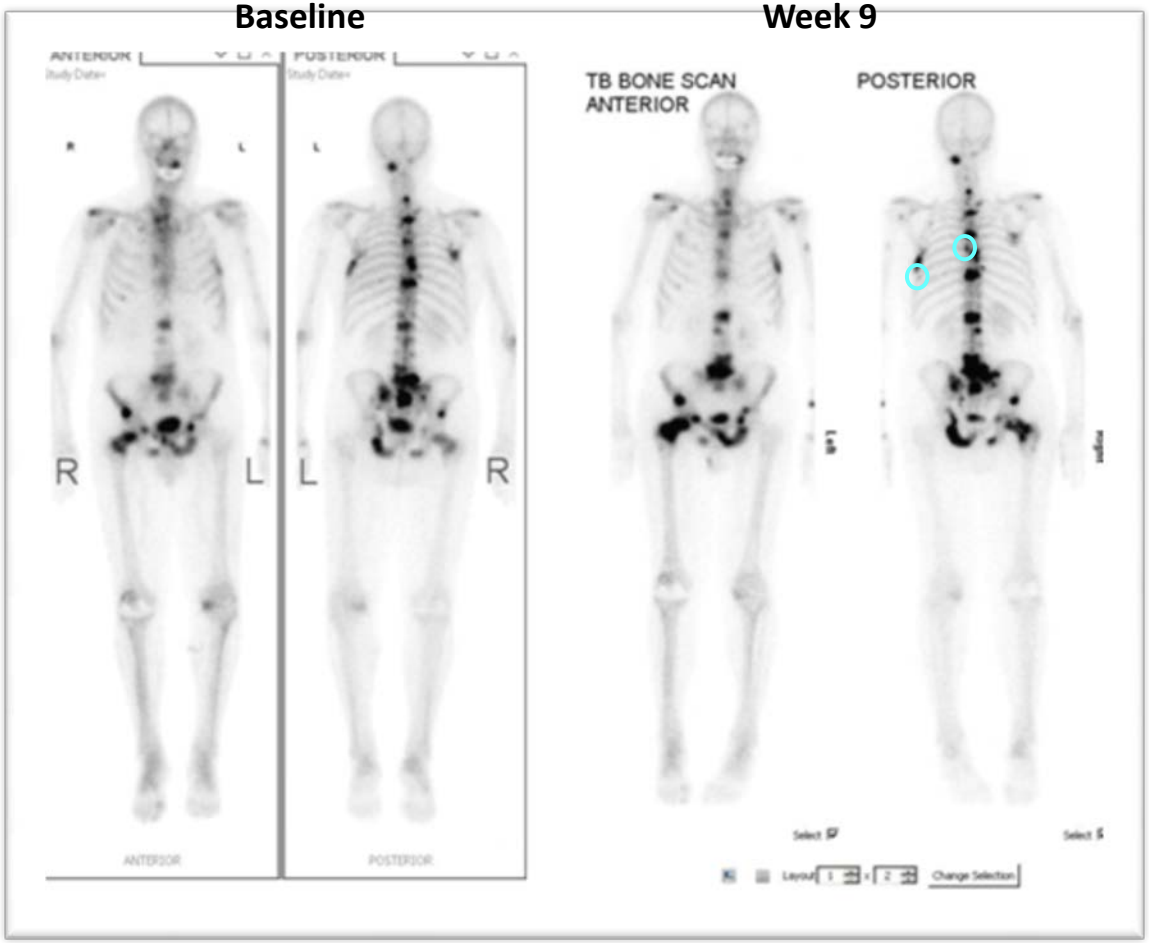
- Patient with > 20 bone lesions at baseline scan
- At the Week 9 visit, patient presented with 2 new bone lesions
- Week 17 & 25 patient did not have new lesions compared to the Week 9 bone scan
- 4 new lesions were detected at Week 37
- Follow-up scans were completed at Week 49, > 5 lesions were detected confirming progression

Scenario 1: Bone Scan Progression



- 2 new lesions at the Week 9, stable until Week 39 meeting progression criteria at Week 49.

Scenario 1: Baseline vs 9 Week



- 2 new lesions at the Week 9 bone scan vs baseline

Scenario 1:
Baseline & Week 9 Assessments

PCCTC Bone Scan Assessment Tool

BASELINE Scan Date: (_____)

Patient Identifier: [redacted]

Protocol Number: [redacted] | Protocol Start Date: [redacted]

Is tracer uptake related to metastatic disease?

(•) Yes ( ) No

NOTE If "NO", do not fill out the form below

If yes, indicate total number of lesions related to metastatic disease (select one)

( ) 1 ( ) 2-4 ( ) 5-9 ( ) 10-20 (•) >20

Comments		Investigator's Signature	[redacted]

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PCCTC Bone Scan Assessment Tool

9 Week Scan Date: ([redacted])

Patient Identifier: [redacted]

Protocol Number: [redacted] | Protocol Start Date: [redacted]

Is tracer uptake related to metastatic disease?

(•) Yes ( ) No

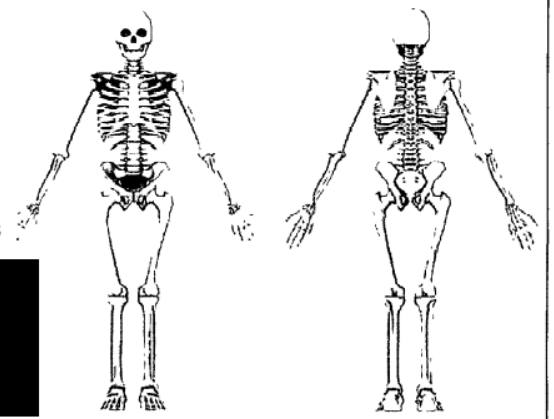
NOTE If "NO", do not fill out the form below

Draw site(s) of NEW lesion(s) on skeleton

Check Region(s) of NEW Disease:

- ☐ Skull
- ■ Thorax
- ■ Spine
- ☐ Pelvis
- ☐ Extremities

[redacted]



If yes, indicate total number of NEW lesions compared to Baseline Scan (Date: [redacted]) (select one)

( ) 0 ( ) 1 (•) 2 ( ) 3 ( ) 4 ( ) 5 ( ) >5

*Presence of new lesions at this time does not confirm progression *

Clinical Impression (circle one)

( ) Improved (•) Stable ( ) Progression

Comments		Investigator's Signature	[redacted]

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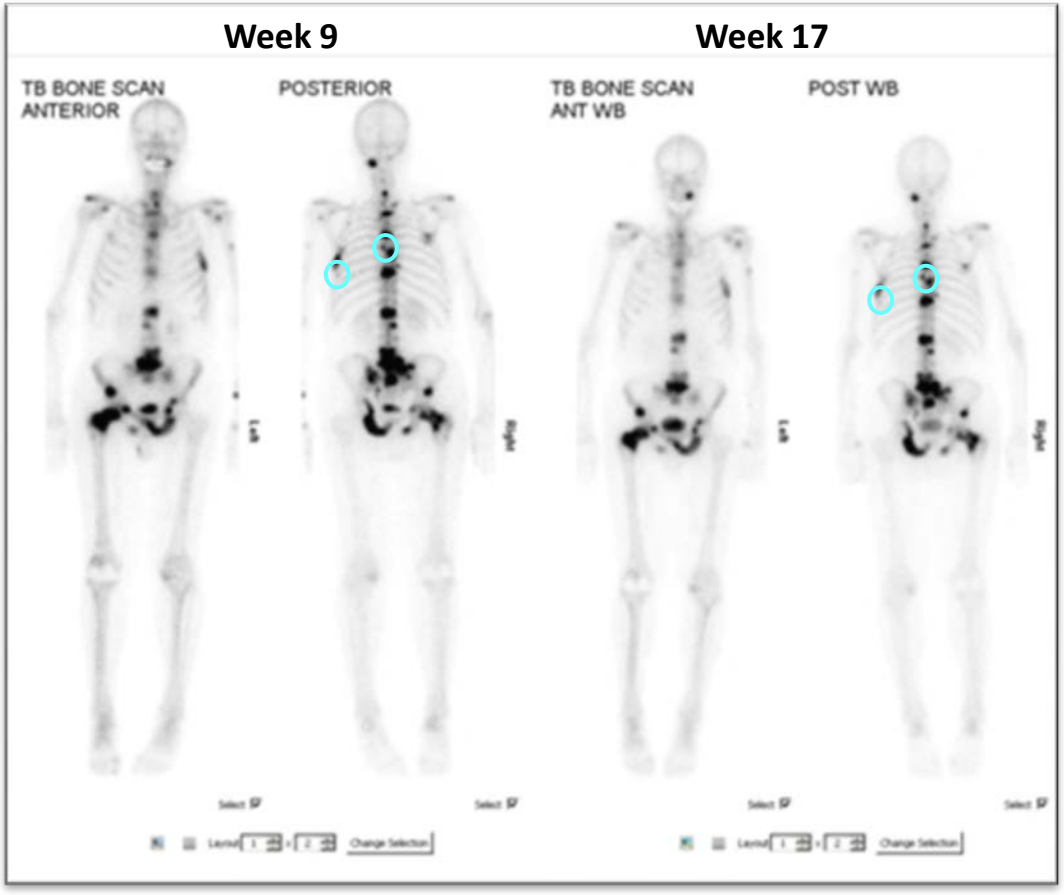
Scenario 1: Week 9 vs Week 17



- No new lesions at Week 17 compared to Week 9

Scenario 1: Week 17 Assessment

PCCTC Bone Scan Assessment Tool

17 Week Scan Date: ( )

To be compared to 9 Week Scan

Patient Identifier: [redacted]

Protocol Number: [redacted] Protocol Start Date: [redacted]

Is tracer uptake related to metastatic disease?

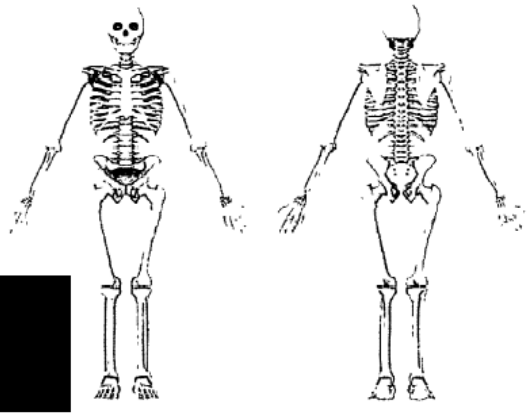
(•) Yes ( ) No

NOTE If "NO", do not fill out the form below

Draw site(s) of NEW lesion(s) on skeleton

Check Region(s) of NEW Disease:

- ☐ Skull
- ☐ Thorax
- ☐ Spine
- ☐ Pelvis
- ☐ Extremitie



[redacted]

If yes, indicate total number of NEW lesions compared to 9 Week Scan (Date: [redacted])

(select one)

(•) 0 ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) >5

Clinical Impression (circle one)

( ) Improved (•) Stable ( ) Progression

Comments		Investigator's Signature	[redacted]

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PCCTC Bone Scan Assessment Tool

Progression Assessment Worksheet

Patient Identifier: [redacted]

Protocol Number: [redacted] Protocol Start Date: [redacted]

Date of Scan: [redacted]

1. Are there 2 or more new lesions compared to the WEEK 9 SCAN?

( ) Yes (•) No

If YES, proceed to question 2.

If NO, the patient does not have radiographic progression by bone scan.

2. Is this the first scan performed POST the WEEK 9 SCAN?

(•) Yes ( ) No

If YES, proceed to question 3A. If NO, proceed to question 3B.

3A. Were there 2 or more new lesions at the WEEK 9 SCAN compared to the BASELINE SCAN?	3B. Does this scan confirm the presence of 2 or more new lesions seen since the WEEK 9 SCAN?
( ) Yes ( ) No	( ) Yes ( ) No

If YES, patient has met conditions for radiographic progression by bone scan.

If NO, the patient does not have radiographic progression by bone scan.

Comments		Investigator's Signature	[redacted]

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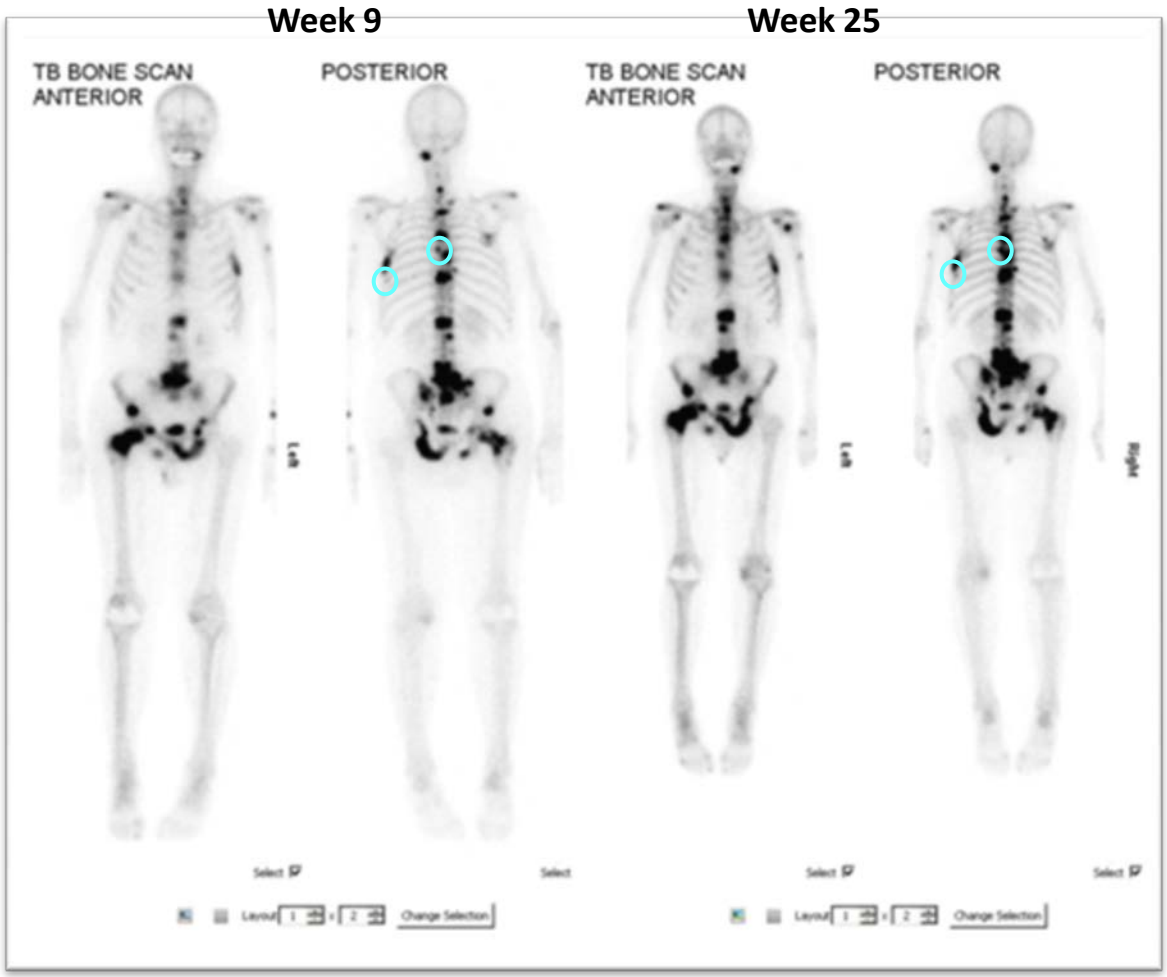
Scenario 1: Week 9 vs Week 25



- No new lesions at Week 25 compared to Week 9

Scenario 1: Week 25 Assessment

PCCTC Bone Scan Assessment Tool

25 Week Scan Date: [redacted]

To be compared to 9 Week Scan

Patient Identifier: [redacted]

Protocol Number: [redacted] Protocol Start Date: [redacted]

Is tracer uptake related to metastatic disease?

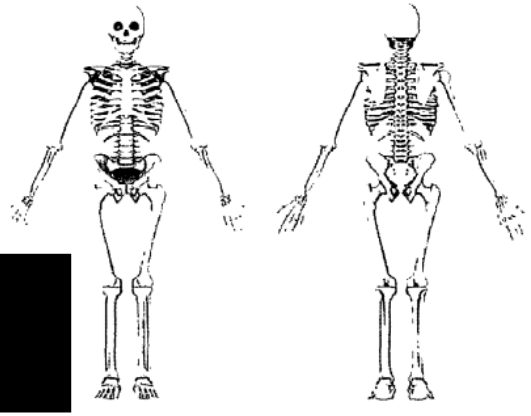
(●) Yes ( ) No

NOTE: If "NO", do not fill out the form below

Draw site(s) of NEW lesion(s) on skeleton

Check Region(s) of NEW Disease:

- ❑ Skull
- ❑ Thorax
- ❑ Spine
- ❑ Pelvis
- ❑ Extremitie



[redacted]

If yes, indicate total number of NEW lesions compared to 9 Week Scan (Date: [redacted])

(select one)

(●)0 ( )1 ( )2 ( )3 ( )4 ( )5 ( )>5

Clinical Impression (circle one)

( ) Improved (●) Stable ( ) Progression

Comments		Investigator's Signature	[redacted]

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PCCTC Bone Scan Assessment Tool

Progression Assessment Worksheet

Patient Identifier: [redacted]

Protocol Number: [redacted] Protocol Start Date: [redacted]

Date of Scan: [redacted]

1. Are there 2 or more new lesions compared to the WEEK 9 SCAN?

( ) Yes (●) No

If YES, proceed to question 2.

If NO, the patient does not have radiographic progression by bone scan.

2. Is this the first scan performed POST the WEEK 9 SCAN?

( ) Yes ( ) No

If YES, proceed to question 3A. If NO, proceed to question 3B.

3A. Were there 2 or more new lesions at the WEEK 9 SCAN compared to the BASELINE SCAN?	3B. Does this scan confirm the presence of 2 or more new lesions seen since the WEEK 9 SCAN?
( ) Yes ( ) No	( ) Yes ( ) No

If YES, patient has met conditions for radiographic progression by bone scan.

If NO, the patient does not have radiographic progression by bone scan.

Comments		Investigator's Signature	[redacted]

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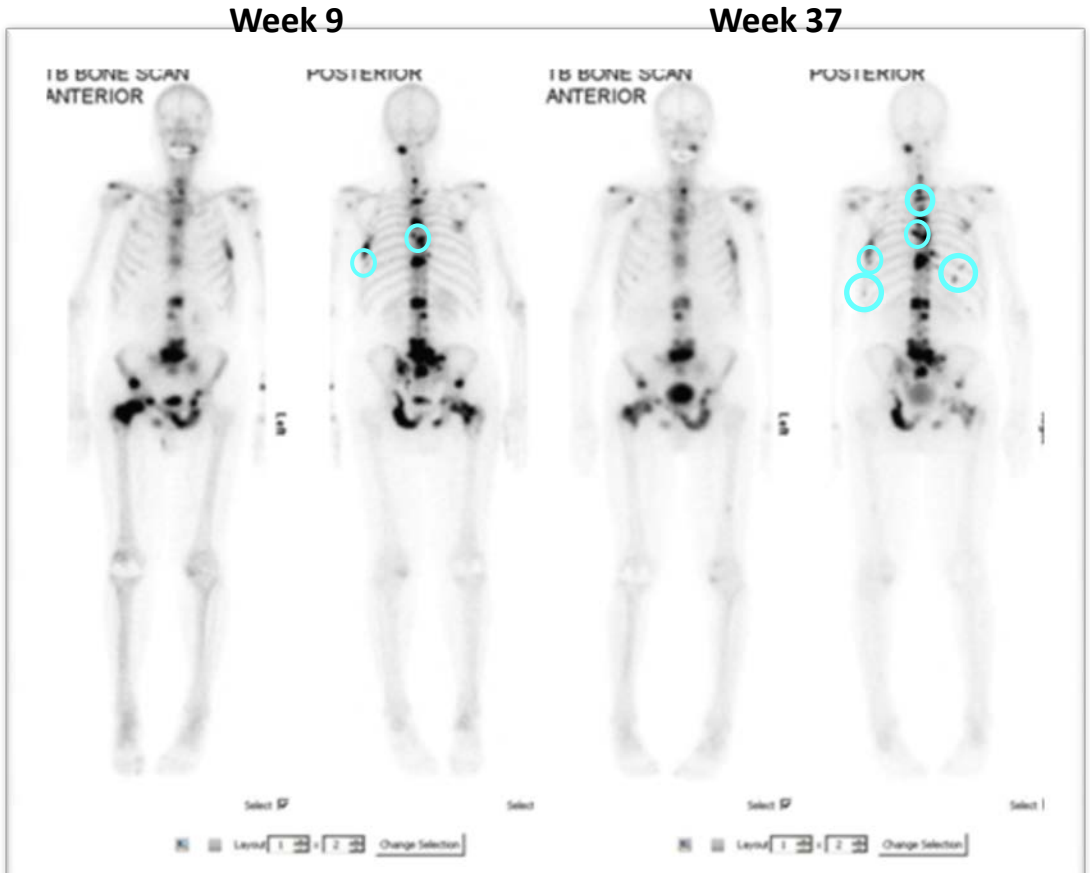
Scenario 1: Week 9 vs Week 37



- 4 new lesions at Week 37 compared to Week 9
  - New lesions at T4, right posteromedial 10th and 11th rib, left lateral 10th rib

Scenario 1: Week 37 Assessment

PCCTC Bone Scan Assessment Tool

37 **Week Scan** Date: (___)

To be compared to 9 Week Scan

Patient Identifier: [redacted]

Protocol Number: [redacted] Protocol Start Date: [redacted]

Is tracer uptake related to metastatic disease?

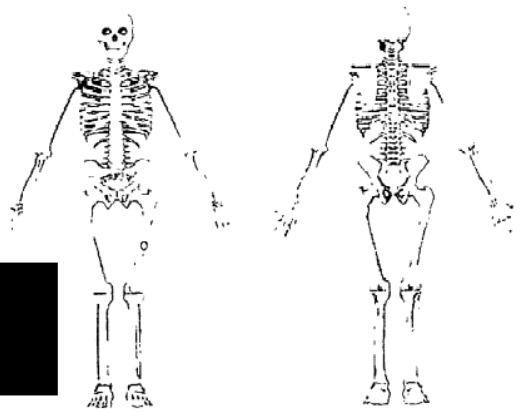
(•) Yes ( ) No

NOTE If "NO", do not fill out the form below

Draw site(s) of NEW lesion(s) on skeleton

Check Region(s) of NEW Disease:

- ☐ Skull
- ■ Thorax
- ■ Spine
- ☐ Pelvis
- ■ Extremitie



[redacted]

If yes, indicate total number of NEW lesions compared to 9 Week Scan (Date: [redacted])

(select one)

( )0 ( )1 ( )2 ( )3 (•)4 ( )5 ( )>5

Clinical Impression (circle one)

( )Improved ( )Stable (•)Progression

Comments		Investigator's Signature	[redacted]

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PCCTC Bone Scan Assessment Tool

Progression Assessment Worksheet

Patient Identifier: [redacted]

Protocol Number: [redacted] Protocol Start Date: [redacted]

Date of Scan: [redacted]

1. Are there 2 or more new lesions compared to the WEEK 9 SCAN?

(•) Yes ( ) No

If YES, proceed to question 2.

If NO, the patient does not have radiographic progression by bone scan.

2. Is this the first scan performed POST the WEEK 9 SCAN?

( ) Yes (•) No

If YES, proceed to question 3A. If NO, proceed to question 3B.

3A. Were there 2 or more new lesions at the WEEK 9 SCAN compared to the BASELINE SCAN?	3B. Does this scan confirm the presence of 2 or more new lesions seen since the WEEK 9 SCAN?
( ) Yes ( ) No	( ) Yes (•) No

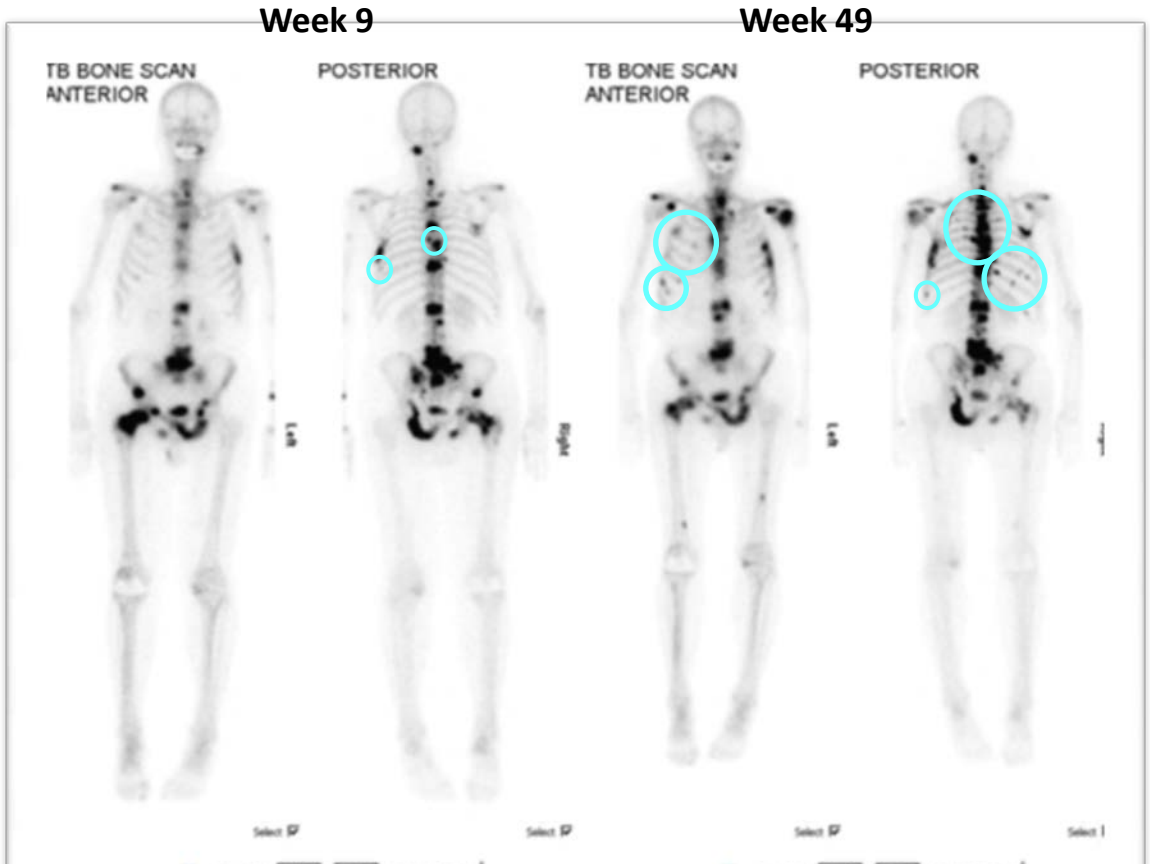
If YES, patient has met conditions for radiographic progression by bone scan.

If NO, the patient does not have radiographic progression by bone scan.

Comments		Investigator's Signature	[redacted]

Version 2 0 © 2010, MSKCC [redacted]

Scenario 1: Week 9 vs Week 49



- >5 new lesions at Week 49 compared to Week 9
  - New lesions in the ribs, scapula, sternum, and distal femurs

Scenario 1: Week 49 Assessment Progression Confirmed

PCCTC Bone Scan Assessment Tool

49 **Week Scan** Date: [redacted]

To be compared to 9 Week Scan

Patient Identifier: [redacted]

Protocol Number: [redacted] Protocol Start Date: [redacted]

Is tracer uptake related to metastatic disease?

(•) Yes ( ) No

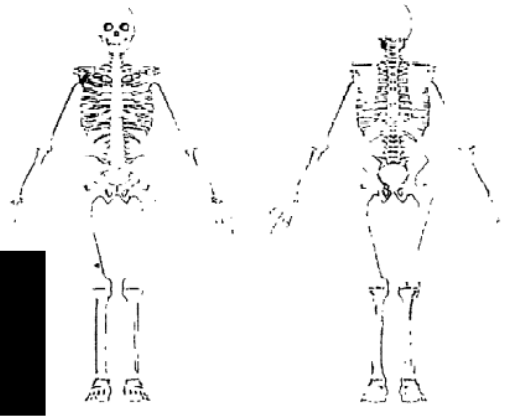
NOTE If "NO", do not fill out the form below

Draw site(s) of NEW lesion(s) on skeleton

Check Region(s) of NEW Disease:

- ☐ Skull
- ■ Thorax
- ■ Spine
- ☐ Pelvis
- ■ Extremitie

[redacted]



If yes, indicate total number of NEW lesions compared to 9 Week Scan (Date: [redacted])

(select one)

( )0 ( )1 ( )2 ( )3 ( )4 ( )5 (•)>5

Clinical Impression (circle one)

( ) Improved ( ) Stable (•) Progression

Comments		Investigator's Signature	[redacted]

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PCCTC Bone Scan Assessment Tool

Progression Assessment Worksheet

Patient Identifier: [redacted]

Protocol Number: [redacted] Protocol Start Date [redacted]

Date of Scan: [redacted]

1. Are there 2 or more new lesions compared to the WEEK 9 SCAN?

(•) Yes ( ) No

If YES, proceed to question 2.

If NO, the patient does not have radiographic progression by bone scan.

2. Is this the first scan performed POST the WEEK 9 SCAN?

( ) Yes (•) No

If YES, proceed to question 3A. If NO, proceed to question 3B.

3A. Were there 2 or more new lesions at the WEEK 9 SCAN compared to the BASELINE SCAN?	3B. Does this scan confirm the presence of 2 or more new lesions seen since the WEEK 9 SCAN?
(•) Yes ( ) No	(•) Yes ( ) No

If YES, patient has met conditions for radiographic progression by bone scan.

If NO, the patient does not have radiographic progression by bone scan.

Comments		Investigator's Signature	[redacted]

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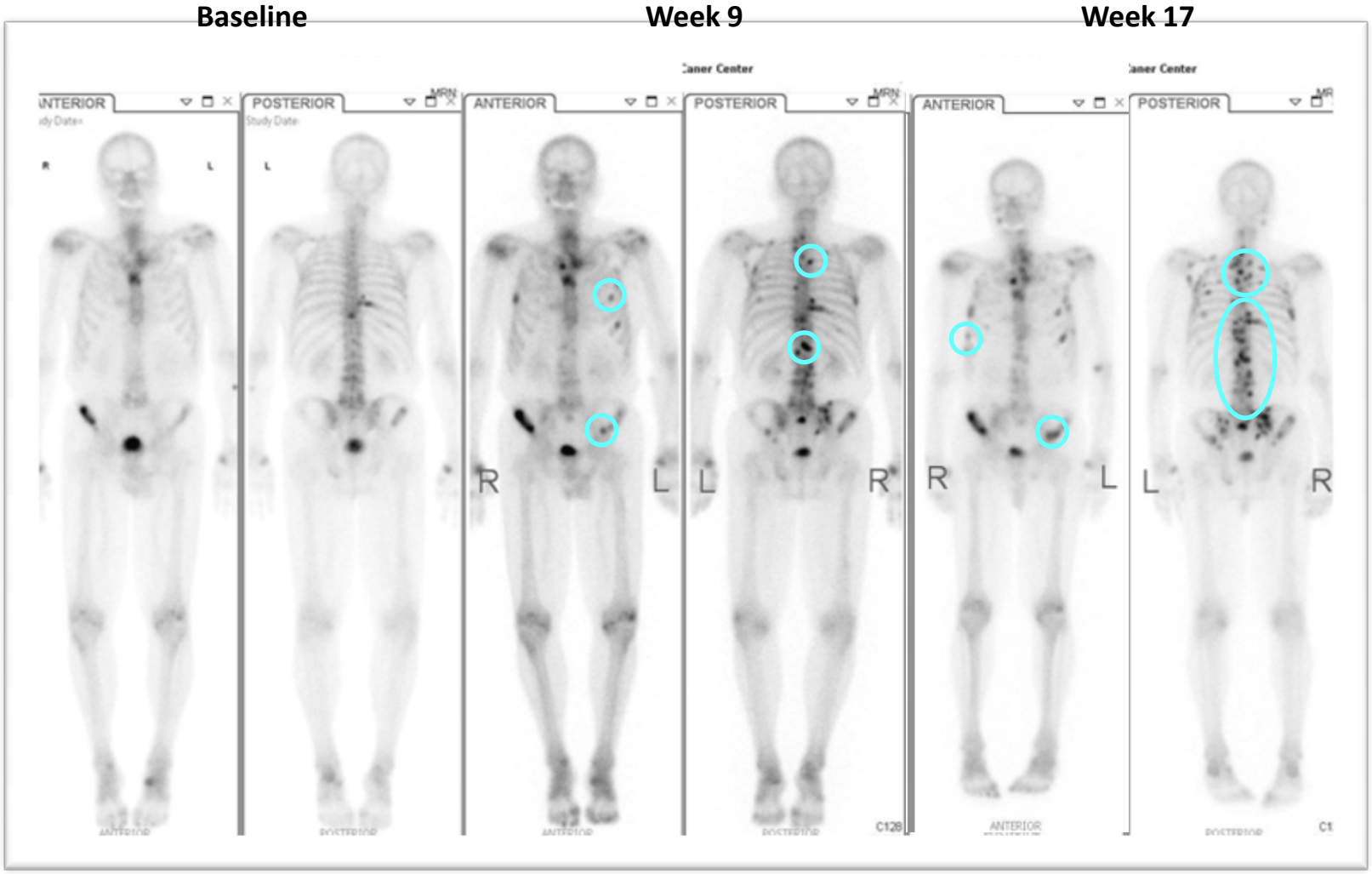
Scenario 2: Early Progression

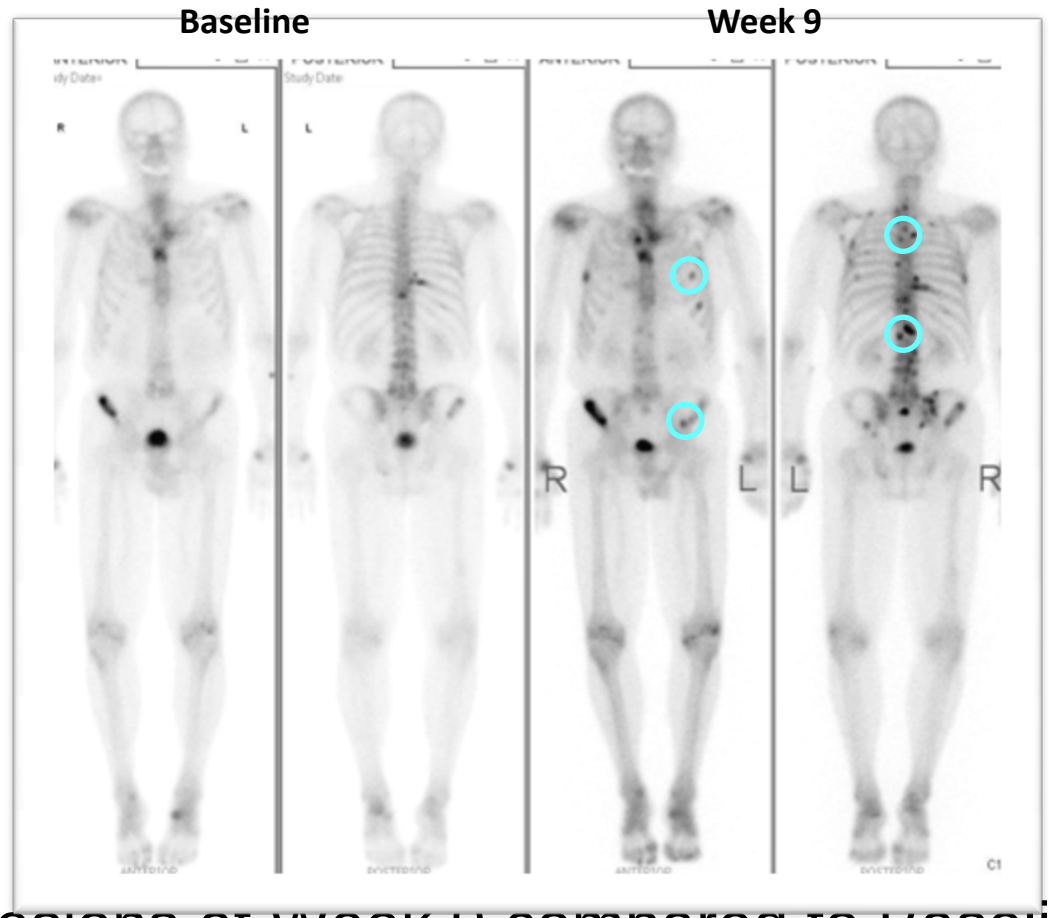
- Patient with 5-9 detectable lesions at baseline scan
- Week 9 bone scan presented with >5 new lesions vs. Baseline bone scan (possible bone scan flare phenomenon)
- At the Week 17 follow up, patient had >5 new lesions compared to the Week 9 bone scan, confirming radiographic progression

Scenario 2: Bone Scan Progression



- Early flare at Wk 9, patient rapidly progressed at Wk 17

Scenario 2: Baseline vs Week 9



- >5 new lesions at Week 9 compared to Baseline
  - Multiple new foci in the spine, bilateral ribs, sternum, scapulae, sacrum, and iliac bones

Scenario 2:
Baseline & Week 9 Assessments

PCCTC Bone Scan Assessment Tool

BASELINE Scan Date: (_____)

Patient Identifier: [redacted]

Protocol Number: [redacted] Protocol Start Date: [redacted]

Is tracer uptake related to metastatic disease?

(•) Yes ( ) No

NOTE If "NO", do not fill out the form below

If yes, indicate total number of lesions related to metastatic disease (select one)

( ) 1 ( ) 2-4 (•) 5-9 ( ) 10-20 ( ) >20

Comments		Investigator's Signature	[redacted]

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PCCTC Bone Scan Assessment Tool

9 Week Scan Date: (_____)

Patient Identifier: [redacted]

Protocol Number: [redacted] Protocol Start Date: [redacted]

Is tracer uptake related to metastatic disease?

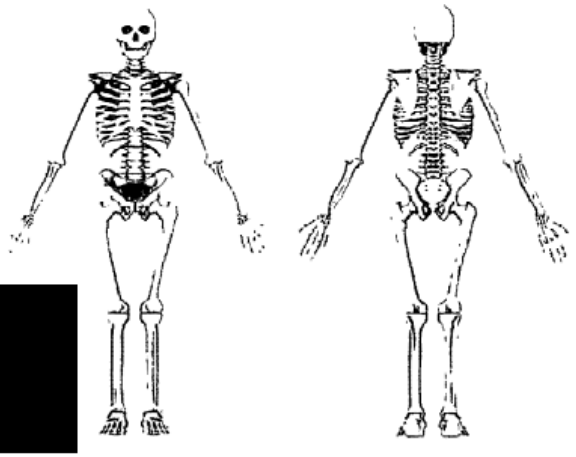
(•) Yes ( ) No

NOTE If "NO", do not fill out the form below

Draw site(s) of NEW lesion(s) on skeleton

Check Region(s) of NEW Disease:

- ☐ Skull
- ■ Thorax
- ■ Spine
- ■ Pelvis
- ☐ Extremities



[redacted]

If yes, indicate total number of NEW lesions compared to Baseline Scan (Date: _____)

(select one)

( ) 0 ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 (•) >5

*Presence of new lesions at this time does not confirm progression *

Clinical Impression (circle one)

( ) Improved ( ) Stable (•) Progression

Comments		Investigator's Signature	[redacted]

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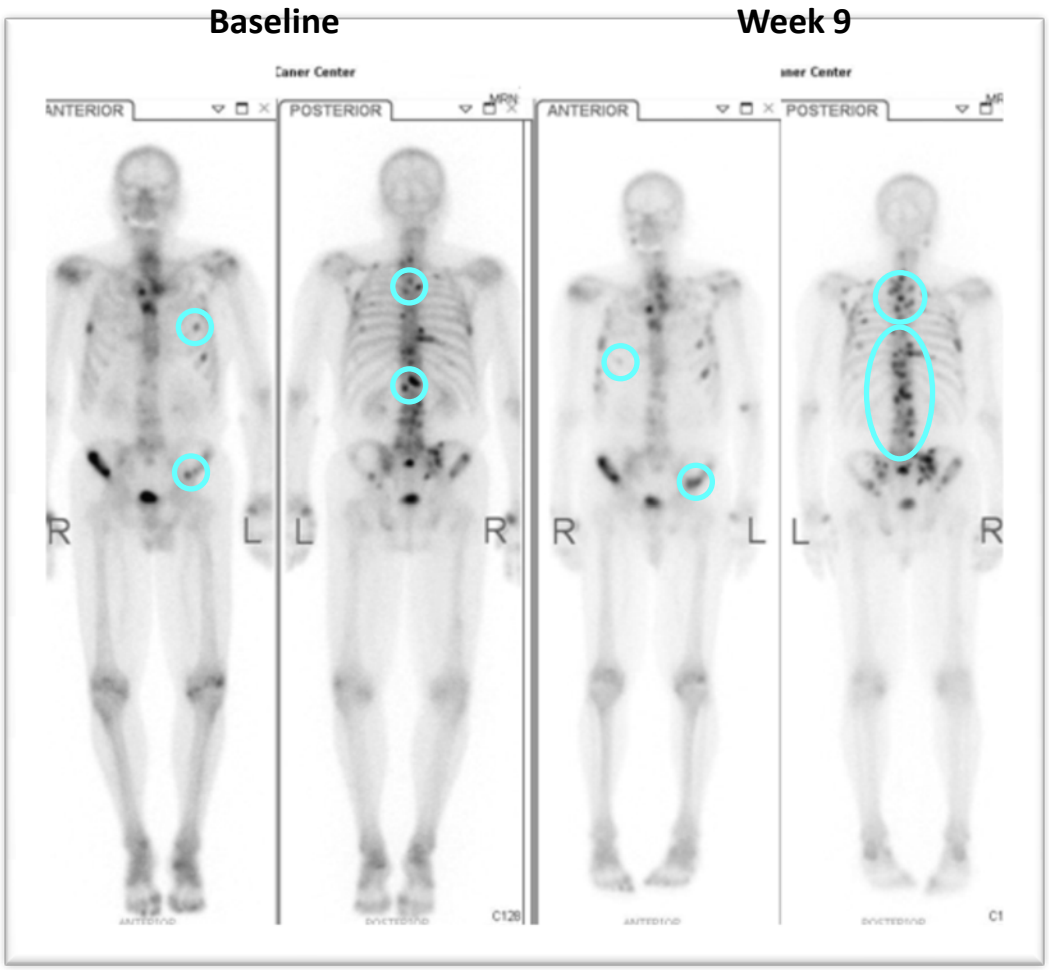
Scenario 2: Week 9 vs Week 17



- >5 new lesions at Week 17 compared to Week 9
  - New uptake in the spine, rib cage, and left hemipelvis

Scenario 2: Wk 17 Assessment Progression Confirmed

PCCTC Bone Scan Assessment Tool

17 **Week Scan** Date: (redacted)

To be compared to 9 Week Scan

Patient Identifier: redacted

Protocol Number: redacted | Protocol Start Date: redacted

Is tracer uptake related to metastatic disease?

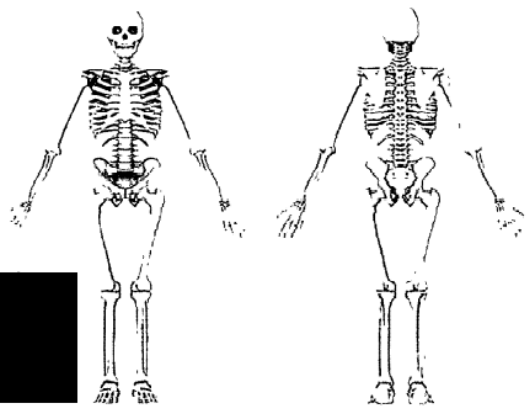
(•) Yes ( ) No

NOTE If "NO", do not fill out the form below

Draw site(s) of NEW lesion(s) on skeleton

Check Region(s) of NEW Disease:

- ☐ Skull
- ■ Thorax
- ■ Spine
- ■ Pelvis
- ☐ Extremitie



redacted

If yes, indicate total number of NEW lesions compared to 9 Week Scan (Date: redacted)

(select one)

( )0 ( )1 ( )2 ( )3 ( )4 ( )5 (•)>5

Clinical Impression (circle one)

( )Improved ( )Stable (•)Progression

Comments		Investigator's Signature	redacted

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PCCTC Bone Scan Assessment Tool

Progression Assessment Worksheet

Patient Identifier: redacted

Protocol Number: redacted | Protocol Start Date: redacted

Date of Scan: redacted

1. Are there 2 or more new lesions compared to the WEEK 9 SCAN?

(•) Yes ( ) No

If YES, proceed to question 2.

If NO, the patient does not have radiographic progression by bone scan.

2. Is this the first scan performed POST the WEEK 9 SCAN?

(•) Yes ( ) No

If YES, proceed to question 3A. If NO, proceed to question 3B.

3A. Were there 2 or more new lesions at the WEEK 9 SCAN compared to the BASELINE SCAN?	3B. Does this scan confirm the presence of 2 or more new lesions seen since the WEEK 9 SCAN?
(•) Yes ( ) No	(•) Yes ( ) No

If YES, patient has met conditions for radiographic progression by bone scan.

If NO, the patient does not have radiographic progression by bone scan.

Comments		Investigator's Signature	redacted

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The PCWG2 Bone Scan Form Guidelines Alliance #A031201

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Contact for Questions