MALIMAR Radiology Reads - CRF Phase 2

Version 4, 06 September 2021

* Required

1. Scan ID *

[   ]

2. Reader ID *

[   ]

3. Round *

◯ Round 1

◯ Round 2

4. Date of Read *

Please input date (dd/MM/yyyy)   🗓

5. Start time of read - Enter in format: HH:MM using 24 hour clock *

6. Disease status - BONES - Record Number of Active / Focal Lesions *

	0	1 - 4	5 - 10	>10
Cervical Spine	◯	◯	◯	◯
Dorsal Spine	◯	◯	◯	◯
Lumbar Spine	◯	◯	◯	◯
Pelvis	◯	◯	◯	◯
Long Bones	◯	◯	◯	◯
Skull	◯	◯	◯	◯
Ribs / Clavicles / Sternum / Scapulae	◯	◯	◯	◯

7. Disease status - BONES - Record maximum size of Active / Focal lesions (mm) *

	<10mm	10 - 20mm	>20mm	Not Applicable, No Focal lesions seen at this site
Cervical Spine	○	○	○	○
Dorsal spine	○	○	○	○
Lumbar spine	○	○	○	○
Pelvis	○	○	○	○
Long Bones (max. long axis)	○	○	○	○
Skull	○	○	○	○
Ribs / Clavicles / Sternum / Scapulae (max. long axis)	○	○	○	○

8. Disease Status - BONES - How confident are you in your assessment of Active / Focal lesions *

	Not at all confident	Some confidence	Confident	Very Confident
Cervical Spine	○	○	○	○
Dorsal Spine	○	○	○	○
Lumbar Spine	○	○	○	○
Pelvis	○	○	○	○
Long Bones	○	○	○	○
Skull	○	○	○	○
Ribs / Clavicles / Sternum / Scapulae	○	○	○	○

9. Disease Status - Record if diffuse disease was present at any of these sites?
   *

	Yes	No
Cervical Spine	○	○
Dorsal Spine	○	○
Lumbar Spine	○	○
Pelvis	○	○
Long Bones	○	○
Skull	○	○
Ribs / Clavicles / Sternum / Scapulae	○	○

10. How confident were you in your assessment of diffuse disease at these sites? *

	Not at all confident	Some confidence	Confident	Very confident
Cervical Spine	○	○	○	○
Dorsal Spine	○	○	○	○
Lumbar Spine	○	○	○	○
Pelvis	○	○	○	○
Long Bones	○	○	○	○
Skull	○	○	○	○
Ribs / Clavicles / Sternum / Scapulae	○	○	○	○

11. Was extramedullary disease present at any site? *

○ Yes

○ No

12. If extramedullary disease was present at any site - state location(s) separated by a semi-colon

[   ]

13. If extramedullary disease was present, what was your level of confidence in assessing this? *

   ○ Not confident at all

   ○ Some confidence

   ○ Confident

   ○ Very confident

   ○ Not Applicable, no extramedullary disease is seen.

14. Confidence in assessing overall disease status on this scan (i.e. in determining the presence or absence of ANY active disease) *

   ○ Not confident at all

   ○ Some confidence

   ○ Confident

   ○ Very confident

15. Stop time of read - RECORD IMMEDIATELY AFTER COMPLETING CLINICAL READ - Enter in format: HH:MM using 24 hour clock *

   [   ]

16. TO BE COMPLETED FOLLOWING THE CLINICAL READ:
    Was a Machine Learning Image available *

   ○ Yes

   ○ No

17. If a Machine Learning 'ML' Image was available, please indicate whether sites were positive for active / focal disease, i.e. was there an ML finding?

	Highly likely negative on ML	Probably negative on ML	Probably positive on ML	Highly likely positive on ML
Cervical Spine	○	○	○	○
Dorsal Spine	○	○	○	○
Lumbar Spine	○	○	○	○
Pelvis	○	○	○	○
Long Bones	○	○	○	○
Skull	○	○	○	○
Ribs / Clavicles / Sternum / Scapulae	○	○	○	○

18. If a Machine Learning 'ML' image was available, please indicate whether sites were positive for diffuse disease, i.e. was there an ML finding?

	Highly likely negative on ML	Probably negative on ML	Probably positve on ML	Highly likely positive on ML
Cervical Spine	○	○	○	○
Dorsal Spine	○	○	○	○
Lumbar Spine	○	○	○	○
Pelvis	○	○	○	○
Long Bones	○	○	○	○
Skull	○	○	○	○
Ribs / Clavicles / Sternum / Scapulae	○	○	○	○

19. Scan Quality: What was the quality of the WB-MRI used for this read? *

	Good	Adequate	Poor
1. B 900	○	○	○
2. ADC	○	○	○
3. T1 sequences	○	○	○

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20. Please enter any specific comments you have on scan quality

21. Reader confirmation: My responses have been accurately reported on this CRF (enter 'yes' if in agreement with this statement) *

○ Yes

○ No

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MALIMAR Radiology Reads - CRF Phase 3

Version 2, 31 March 2022

* Required

1. Scan ID Post Treatment Scan (PT) *

   [   ]

2. Scan ID - Baseline Scan (BL) *

   [   ]

3. Reader ID *

   [   ]

4. Phase 3 - Round *

   ◯ Round 1

   ◯ Round 2

3/31/2022

5. Date of Read *

[📅]

Format: M/d/yyyy

6. Start time of read - Enter in format: HH:MM using 24 hour clock *

[   ]

7. CERVICAL SPINE - Number of Active / Focal Lesions *

	0	1 - 4	5 - 10	>10
Post Treatment	○	○	○	○
Baseline	○	○	○	○

8. CERVICAL SPINE - Maximum size (mm) of Active / Focal Lesions *

	<10mm	10 - 20mm	>20mm	Not Applicable, No Focal lesions seen at this site
Post-Treatment	○	○	○	○
Baseline	○	○	○	○

9. CERVICAL SPINE - Was Diffuse Disease present?   *

	Yes	No
Post Treatment	○	○
Baseline	○	○

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10. DORSAL SPINE - Number of Active / Focal Lesions *

	0	1 - 4	5 - 10	>10
Post Treatment	○	○	○	○
Baseline	○	○	○	○

11. DORSAL SPINE - Maximum size (mm) of Active / Focal Lesions *

	<10mm	10 - 20mm	>20mm	Not Applicable, No Focal lesions seen at this site
Post-Treatment	○	○	○	○
Baseline	○	○	○	○

12. DORSAL SPINE - Was Diffuse Disease present? *

	Yes	No
Post Treatment	○	○
Baseline	○	○

13. LUMBAR SPINE - Number of Active / Focal Lesions *

	0	1 - 4	5 - 10	>10
Post Treatment	○	○	○	○
Baseline	○	○	○	○

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14. LUMBAR SPINE - Maximum size (mm) of Active / Focal Lesions *

	<10mm	10 - 20mm	>20mm	Not Applicable, No Focal lesions seen at this site
Post-Treatment	○	○	○	○
Baseline	○	○	○	○

15. LUMBAR SPINE - Was Diffuse Disease present? *

	Yes	No
Post Treatment	○	○
Baseline	○	○

16. PELVIS - Number of Active / Focal Lesions *

	0	1 - 4	5 - 10	>10
Post Treatment	○	○	○	○
Baseline	○	○	○	○

17. PELVIS - Maximum size (mm) of Active / Focal Lesions *

	<10mm	10 - 20mm	>20mm	Not Applicable, No Focal lesions seen at this site
Post-Treatment	○	○	○	○
Baseline	○	○	○	○

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18. PELVIS - Was Diffuse Disease present?   *

	Yes	No
Post Treatment	○	○
Baseline	○	○

19. LONG BONES - Number of Active / Focal Lesions *

	0	1 - 4	5 - 10	>10
Post Treatment	○	○	○	○
Baseline	○	○	○	○

20. LONG BONES - Maximum size (mm) of Active / Focal Lesions *

	<10mm	10 - 20mm	>20mm	Not Applicable, No Focal lesions seen at this site
Post-Treatment	○	○	○	○
Baseline	○	○	○	○

21. LONG BONES - Was Diffuse Disease present?   *

	Yes	No
Post Treatment	○	○
Baseline	○	○

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22. SKULL - Number of Active / Focal Lesions *

	0	1 - 4	5 - 10	>10
Post Treatment	○	○	○	○
Baseline	○	○	○	○

23. SKULL - Maximum size (mm) of Active / Focal Lesions *

	<10mm	10 - 20mm	>20mm	Not Applicable, No Focal lesions seen at this site
Post-Treatment	○	○	○	○
Baseline	○	○	○	○

24. SKULL - Was Diffuse Disease present?   *

	Yes	No
Post Treatment	○	○
Baseline	○	○

25. RIBS / CLAVICLES / STERNUM / SCAPULAE - Number of Active / Focal Lesions *

	0	1 - 4	5 - 10	>10
Post Treatment	○	○	○	○
Baseline	○	○	○	○

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26. RIBS / CLAVICLES / STERNUM / SCAPULAE - Maximum size (mm) of Active / Focal Lesions *

	<10mm	10 - 20mm	>20mm	Not Applicable, No Focal lesions seen at this site
Post-Treatment	○	○	○	○
Baseline	○	○	○	○

27. RIBS / CLAVICLES / STERNUM / SCAPULAE - Was Diffuse Disease present?   *

	Yes	No
Post Treatment	○	○
Baseline	○	○

28. Was extramedullary disease present at any site? *

○ Yes

○ No

29. If extramedullary disease was present at any site - state location(s) separated by a semi-colon

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30. If extramedullary disease was present, what was your level of confidence in assessing this? *

   ◯ Not confident at all

   ◯ Some confidence

   ◯ Confident

   ◯ Very confident

   ◯ Not Applicable, no extramedullary disease is seen.

31. OVERALL RESPONSE - Change in Disease Status (Baseline - Post-Treatment) *

	Complete Response	Partial Response	Stable Disease	Disease Progression
Response category	◯	◯	◯	◯

32. OVERALL RESPONSE - CONFIDENCE - How confident were you in assessing overall response? *

	Not at all confident	Some confidence	Confident	Very confident
Confidence category	◯	◯	◯	◯

33. Stop time of read - RECORD IMMEDIATELY AFTER COMPLETING CLINICAL READ - Enter in format: HH:MM using 24 hour clock *

   [   ]

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34. TO BE COMPLETED FOLLOWING THE CLINICAL READ:
    Was a Machine Learning Image available *

    ◯ Yes

    ◯ No

35. If Machine Learning 'ML' Images were available, please indicate category of response suggested by ML

	Complete Response	Partial Response	Stable Disease	Progressive Disease
Response category	◯	◯	◯	◯

36. Scan Quality: What was the quality of the WB-MRI used for this read? *

	Good	Adequate	Poor
1. B 900	◯	◯	◯
2. ADC	◯	◯	◯
3. T1 sequences	◯	◯	◯

37. Please enter any specific comments you have on scan quality

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38. Reader confirmation: My responses have been accurately reported on this CRF (enter 'yes' if in agreement with this statement) *

○ Yes

○ No

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