



RECIST Overview

Knowledge Assessment

Key Pad Question 1

Which of the following is considered a Target Lesion at baseline ?

- A. A lung lesion measuring 15 mm by spiral CT scan
- B. A liver lesion measuring 18 mm in LD by conventional CT scan
- C. A previously irradiated lesion in the lung measuring 22 mm by spiral CT scan
- D. Bone lesion

Key Pad Question 1 - Answer

Which of the following is considered a Target Lesion at baseline ?

- A. A lung lesion measuring 15 mm by spiral CT scan
- B. A liver lesion measuring 18 mm in LD by conventional CT scan
- C. A previously irradiated lesion in the lung measuring 22 mm by spiral CT scan
- D. Bone lesion

Key Pad Question 2

The Investigator has detected a possible new lesion (very faint on the scan) but they are not sure if it is actually a new lesion. What should they do ?

- A. Record the lesion as a new lesion and discontinue the patients treatment
- B. Record the lesion as a new lesion but continue treatment
- C. Continue treatment until the next scheduled RECIST visit. If new lesion is confirmed record new lesion at this visit and discontinue treatment
- D. Continue treatment until the next scheduled RECIST visit. If new lesion is confirmed record new lesion at the previous visit and discontinue treatment

Key Pad Question 2 - Answer

The Investigator has detected a possible new lesion (very faint on the scan) but they are not sure if it is actually a new lesion. What should they do ?

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- D. Continue treatment until the next scheduled RECIST visit. If new lesion is confirmed record new lesion at the previous visit and discontinue treatment

Key Pad Question 3

Patient has an overall visit response of PR.
When should a confirmation scan be performed ?

- A. No confirmation scan is required for a PR
- B. Confirmation of response should occur within 4 weeks of first documented PR
- C. Confirmation should occur at the next scheduled visit but certainly no less than 4 weeks from first documented response
- D. Response can be confirmed at any time

Key Pad Question 3 - Answer

Patient has an overall visit response of PR.
When should a confirmation scan be performed ?

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- B. Confirmation of response should occur within 4 weeks of first documented PR
- C. Confirmation should occur at the next scheduled visit but certainly no less than 4 weeks from first documented response
- D. Response can be confirmed at any time

Key Pad Question 4

Which of the following would not necessarily be classed as progressive Disease ?

- A. A new measurable lesion
- B. An individual TL that has increased 30% compared to a previous assessment
- C. A 25% increase in the sum of LD of TLs compared to previous minimum sum of LDs
- D. Progression of NTLs

Key Pad Question 4 - Answer

Which of the following would not necessarily be classed as progressive Disease ?

- A. A new measurable lesion
- B. An individual TL that has increased 30% compared to a previous assessment
- C. A 25% increase in the sum of LD of TLs compared to previous minimum sum of LDs
- D. Progression of NTLs

Key Pad Question 5

Patient has TL and NTL at baseline. At one of the follow up visits the TLs are not assessed. What would be the patients overall visit response ?

- A. Overall response will be based on assessment of NTLs only
- B. No overall response should be provided
- C. Overall response will always be NE
- D. Overall response will be assigned NE, unless there is evidence of progression of NTL or a new lesion, in which case progressive disease would be assigned

Key Pad Question 5 - Answer

Patient has TL and NTL at baseline. At one of the follow up visits the TLs are not assessed. What would be the patients overall visit response ?

- A. Overall response will be based on assessment of NTLs only
- B. No overall response should be provided
- C. Overall response will always be NE
- D. Overall response will be assigned NE, unless there is evidence of progression of NTL or a new lesion, in which case progressive disease would be assigned

Key Pad Question 6

Which of these would result in an overall visit response of PR ?

- A. TL=PR, NTL=NE, New lesion=No
- B. TL=PR, NTL=Incomplete response/SD, New lesion=Yes
- C. TL=PR, NTL=Incomplete response/SD, New lesion=No
- D. TL=PR, NTL=CR, New lesion=Yes

Key Pad Question 6 - Answer

Which of these would result in an overall visit response of PR ?

- A. TL=PR, NTL=NE, New lesion=No
- B. TL=PR, NTL=Incomplete response/SD, New lesion=Yes
- C. TL=PR, NTL=Incomplete response/SD, New lesion=No
- D. TL=PR, NTL=CR, New lesion=Yes

Key Pad Question 7

A patient has a previously irradiated lesion prior to entry into the trial. How should this be recorded at baseline ?

- A. Previously irradiated lesion do not need to be recorded at baseline
- B. If measurable then record as a TL and provide size
- C. Always Record as a NTL
- D. Record as TL but do not provide a size

Key Pad Question 7 - Answer

A patient has a previously irradiated lesion prior to entry into the trial. How should this be recorded at baseline ?

- A. Previously irradiated lesion do not need to be recorded at baseline
- B. If measurable then record as a TL and provide size
- C. **Always Record as a NTL**
- D. Record as TL but do not provide a size

Key Pad Question 8

When a target lesion splits into two lesions, how should this be recorded on the CRF ?

- A. For the TL size, measure the LD of both lesions and record the sum of LDs
- B. Record the additional lesion as an extra TL
- C. Record the LD of the largest lesion and record the smallest lesion as a new lesion
- D. Record the TL as no longer measurable

Key Pad Question 8 - Answer

When a target lesion splits into two lesions, how should this be recorded on the CRF ?

- A. For the TL size, measure the LD of both lesions and record the sum of LDs
- B. Record the additional lesion as an extra TL
- C. Record the LD of the largest lesion and record the smallest lesion as a new lesion
- D. Record the TL as no longer measurable

Key Pad Question 9

If a target lesion becomes too small to accurately measure at a follow-up assessment how should it be recorded ?

- A. Record measurement as 0 mm
- B. Select 'lesion too small to measure' and record longest diameter as 1 mm
- C. Select 'lesion too small to measure' and leave longest diameter blank
- D. Select 'lesion too small to measure' and record longest diameter as the size below which the tumour cannot be accurately measured

Key Pad Question 9 - Answer

If a target lesion becomes too small to accurately measure at a follow-up assessment how should it be recorded ?

- A. Record measurement as 0 mm
- B. Select 'lesion too small to measure' and record longest diameter as 1 mm
- C. Select 'lesion too small to measure' and leave longest diameter blank
- D. Select 'lesion too small to measure' and record longest diameter as the size below which the tumour cannot be accurately measured

Key Pad Question 10

Which non-target lesion response should be recorded at follow up when there are no non-target lesions recorded at baseline ?

- A. Not Evaluable
- B. Complete Response
- C. Not Applicable
- D. Incomplete Response/Stable Disease

Key Pad Question 10 - Answer

Which non-target lesion response should be recorded at follow up when there are no non-target lesions recorded at baseline ?

- A. Not Evaluable
- B. Complete Response
- C. **Not Applicable**
- D. Incomplete Response/Stable Disease

Key Pad Question 11

Which two categories are used to define and document lesions at baseline ?

- A. Big and small
- B. Stable and unstable
- C. Target and non-target
- D. Responsive and progressive

Key Pad Question 11 — Answer

Which two categories are used to define and document lesions at baseline ?

- A. Big and small
- B. Stable and unstable
- C. Target and non-target
- D. Responsive and progressive

Key Pad Question 12

How many target lesions should be identified per patient ?

- A. Up to 10 measurable lesions representative of all involved organs, and no more than 3 lesions per organ
- B. Up to 10 measurable lesions representative of all involved organs, and no more than 5 lesions per organ
- C. Up to 20 measurable lesions representative of all involved organs, and no more than 5 lesions per organ
- D. 42

Key Pad Question 12 - Answer

How many target lesions should be identified per patient ?

- A. Up to 10 measurable lesions representative of all involved organs, and no more than 3 lesions per organ
- B. Up to 10 measurable lesions representative of all involved organs, and no more than 5 lesions per organ
- C. Up to 20 measurable lesions representative of all involved organs, and no more than 5 lesions per organ
- D. 42

Key Pad Question 13

If a target lesion truly disappears and then reappears at a subsequent assessment how should it be recorded ?

- A. Record a target lesion longest diameter of 0 mm and record a new lesion
- B. Record the current longest diameter of the target lesion
- C. Select 'lesion not evaluable' and leave the longest diameter blank
- D. Record the current longest diameter of the target lesion and record a new lesion

Key Pad Question 13 - Answer

If a target lesion truly disappears and then reappears at a subsequent assessment how should it be recorded ?

- A. Record a target lesion longest diameter of 0 mm and record a new lesion
- B. Record the current longest diameter of the target lesion
- C. Select 'lesion not evaluable' and leave the longest diameter blank
- D. Record the current longest diameter of the target lesion and record a new lesion

Key Pad Question 14

Which of the following should be used for measuring target lesions on chest, abdomen and pelvis with conventional CT ?

- A. Cuts of 10 mm or less in slice thickness contiguously
- B. A 5 mm contiguous reconstruction algorithm
- C. Cuts of 5 mm or less in slice thickness contiguously
- D. A 1 mm contiguous reconstruction algorithm

Key Pad Question 14 — Answer

Which of the following should be used for measuring target lesions on chest, abdomen and pelvis with conventional CT ?

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- B. A 5 mm contiguous reconstruction algorithm
- C. Cuts of 5 mm or less in slice thickness contiguously
- D. A 1 mm contiguous reconstruction algorithm

Key Pad Question 15

Which of the following are not RECIST allowed methods of assessment for target lesions ?

- A. CT
- B. MRI
- C. Clinical Examination
- D. PET

Key Pad Question 15 - Answer

Which of the following are not RECIST allowed methods of assessment for target lesions ?

- A. CT
- B. MRI
- C. Clinical Examination
- D. **PET**

Key Pad Question 16

How do you calculate the baseline sum of longest diameters (LD) ?

- A. The sum of the longest diameters for all measurable lesions
- B. The sum of the longest diameters for all target and non-target lesions
- C. The sum of the longest diameters for all target lesions
- D. The sum of the longest diameters for all measurable lesions minus the sum of the longest diameters for target lesions

Key Pad Question 16 - Answer

How do you calculate the baseline sum of longest diameters (LD) ?

- A. The sum of the longest diameters for all measurable lesions
- B. The sum of the longest diameters for all target and non-target lesions
- C. **The sum of the longest diameters for all target lesions**
- D. The sum of the longest diameters for all measurable lesions minus the sum of the longest diameters for target lesions

Key Pad Question 17

What is used as a reference point in the assessment of Progressive Disease in target lesions ?

- A. The baseline sum of longest diameter (LD)
- B. The smallest sum of LD recorded
- C. The largest sum of LD recorded
- D. The median sum of LD recorded

Key Pad Question 17 — Answer

What is used as a reference point in the assessment of Progressive Disease in target lesions ?

- A. The baseline sum of longest diameter (LD)
- B. The smallest sum of LD recorded
- C. The largest sum of LD recorded
- D. The median sum of LD recorded

Key Pad Question 18

A patient discontinues treatment prior to progression. Which procedure should be followed ?

- A. No further RECIST assessments required
- B. A final RECIST assessment should be performed at the discontinuation visit
- C. Patients should continue to have their regular RECIST assessments until documented progression
- D. Continual RECIST assessments should be performed but the investigator can perform the scans at any time

Key Pad Question 18 — Answer

A patient discontinues treatment prior to progression. Which procedure should be followed ?

- A. No further RECIST assessments required
- B. A final RECIST assessment should be performed at the discontinuation visit
- C. Patients should continue to have their regular RECIST assessments until documented progression
- D. Continual RECIST assessments should be performed but the investigator can perform the scans at any time

Key Pad Question 19

A patient discontinues treatment prior to progression but goes on to receive a subsequent cancer therapy. Which procedure should be followed ?

- A. No further RECIST assessments required as patient has discontinued study treatment
- B. No further RECIST assessments required since the patient has started a subsequent therapy
- C. RECIST assessments should be performed until subject receives a subsequent therapy, then no further assessments are needed
- D. Patients should continue to have their regular scheduled RECIST assessments until documented progression, even after they receive a subsequent therapy

Key Pad Question 19 - Answer

A patient discontinues treatment prior to progression but goes on to receive a subsequent cancer therapy. Which procedure should be followed ?

- A. No further RECIST assessments required as patient has discontinued study treatment
- B. No further RECIST assessments required since the patient has started a subsequent therapy
- C. RECIST assessments should be performed until subject receives a subsequent therapy, then no further assessments are needed
- D. Patients should continue to have their regular scheduled RECIST assessments until documented progression, even after they receive a subsequent therapy

Key Pad Question 20

What is used as a reference point in the assessment of Partial Response in target lesions ?

- A. The baseline sum of longest diameter (LD)
- B. The smallest sum of LD recorded
- C. The largest sum of LD recorded
- D. The median sum of LD recorded

Key Pad Question 20 - Answer

What is used as a reference point in the assessment of Partial Response in target lesions ?

- A. The baseline sum of longest diameter (LD)
- B. The smallest sum of LD recorded
- C. The largest sum of LD recorded
- D. The median sum of LD recorded