Imaging Metrics for Trials: Treatment Response Evaluation Frequently Asked Questions

Purpose

To describe the Department of Radiology's procedure for special circumstances related to Imaging Metrics for Trials (IM4T) requests, reports, and inquiries.

IM4T functions as an independent response adjudicator, offering expert, unbiased evaluation assessments to support consistent treatment response evaluation. Clinical radiology reports and IM4T reports are therefore related and often similar, but they can diverge at times. IM4T maintains that clinical decisions should be based on the clinical reads, and trial decisions should be based on RECIST. The two reports should not be used interchangeably.

Scope

Applies to internal and external researchers involved in cancer research studies that require treatment response evaluation using Response Evaluation Criteria in Solid Tumors **(RECIST),** its variants, or other non-RECIST evaluation criteria.

Frequently Asked Questions

Q: IM4T reports cannot be completed until a clinical read has been issued for the related imaging. Who is responsible for expediting clinical reads if there is a special need?

A: The study team is responsible for expediting the clinical read. The IM4T report will be provided within 24hours of finalization of the clinical read. If the IM4T report is needed at a specific time (ex: upcoming provider visit) and the clinical read is not yet signed, the study team should request expedition of the clinical read by sending an email to "ISSS" isss@groups.utsouthwestern.edu. The reading room navigators are available from 8am to 730pm daily and will expedite the clinical read.
If the study team has requested a STAT report, the IM4T coordinator will facilitate the clinical read expedition.

Q: What happens when the clinical read and IM4T report are not in alignment?

A: When a disagreement arises between the two reports that impacts both clinical care and trial management, study team should contact IM4T at RadIM4T@UTSouthwestern.edu and describe the situation in detail as related to the study protocol. The IM4T core personnel will review the disagreement and coordinate the next steps as needed.

The study team should not contact the senior radiologist who performed the read directly. All communication must go through the main email to ensure appropriate documentation and traceability.

The study team is responsible for documenting treatment decisions per Good Clinical Practice should a discrepancy occur.

Q: How does the standard process differ for an outside scan?

A: It does not - the outside images and their report will need to be available in Sectra/EPIC prior to the IM4T report being completed. The study team should request the images/report from the outside facility per their standard practice.

Q: What happens if there is an error or change needed to a read request?

A: When a study team notices they have made an error or a change is needed on the Read Request Submission Form, they should immediately reach out to RADIM4T@UTSouthwestern.edu with the corrected/updated form.

Common errors include:

- Incorrect, incomplete, or omitted radiation/treatment history
- Incorrect or rescheduled imaging dates
- Omitted or incomplete protocol specifications for treated lesions
- Undefined abbreviations
- Omitted variant (RECIST 1.1 & iRECIST)

If the IM4T report has not been initiated, the request will be updated upon receipt.
If the IM4T report has been initiated or completed, the re-read will be considered a new request and billed accordingly.

Q: What happens if a patient transfers onto a study at non-traditional timepoints?

A: For patients who have had baseline and/or post-treatment timepoints already reported by a non-IM4T reader:

- Images and response evaluation report for the last timepoint by the non-IM4T reader must be made available to IM4T to inform IM4T radiologists of the designated target and nontarget lesions.
- If response evaluation report is not available or does not meet the quality standard of IM4T in the opinion of the IM4T radiologist (e.g. incorrect measurement), the current time point request will be rejected and the study PI will be notified.
- IM4T will provide limited interpretation for the current and future timepoints (see below for details). The baseline and any other historical timepoints will not be re-interpreted.
- MINT Lesion™ will *not* be used. The IM4T reader will measure the lesions manually and enter the data into the spreadsheet. Previous measurements will not be copied into the spreadsheet.
- Based on the target and nontarget lesions described in the last response evaluation report, IM4T radiologists will interpret the current timepoint, but only for target lesion size(s) and nontarget response. The overall response will not be reported by IM4T, as IM4T is not responsible for the accuracy of the previous response evaluation by non-IM4T readers. The study PI is responsible for assigning overall response category based on the current timepoint data provided by IM4T.
- IM4T will charge for one interpretation for each requested timepoint(s).

For patients who are transitioning from one trial to another:

- IM4T will provide baseline and subsequent timepoints for the new trial using MINT Lesion™.
- A new baseline interpretation is necessary for the new trial, regardless of whether the images were interpreted as a post-treatment timepoint on a previous trial.
- IM4T will charge standard pricing for all interpretations.

For patients who require image interpretation for trial eligibility (i.e. patient not yet enrolled in a protocol):

- Enrolling study team may request interpretation for determination of measurable disease.
- If eligibility assessment requires establishment of disease progression on prior trial, the study team need to request interpretation of all timepoints necessary to establish progressive disease.
- IM4T will provide eligibility reads on MINT Lesion™.
- IM4T will charge standard pricing for each requested timepoints.

Definitions/Abbreviations

DICOM: Digital Imaging and Communication in Medicine
MOU: Memorandum of Understanding
RCRO: Radiology Clinical Research Office
RECIST: Response evaluation criteria in solid tumors
IM4T: Imaging Metrics for Trials
PI: Principal Investigator