

10 Tips for Using RECIST 1.1 in the Community Setting

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As clinical trials coordinators in a large community-based hospital system in North Carolina, we use Response Evaluation Criteria in Solid Tumors (RECIST 1.1)¹ guidelines for evaluation of the disease state of oncology patients on clinical trials. In this article, we offer 10 tips for coordinating RECIST 1.1 at a community hospital. The information shared here is a culmination of our experience with RECIST tracking and the tool we utilize to accomplish this task. We offer this guidance to other community research programs to set them up for success, with the understanding that every research site is different and that some of the information may not apply to your specific situation.

Tip 1. Use the Same Reading Radiologist or a Core Group of Radiologists

FirstHealth of the Carolinas has approximately 20 reading radiologists. It's optimal to have dedicated staff or at least a core group of radiologists to read for consistency. Depending on your resources, this may not be possible.

Tip 2. Screening Scan: Standard of Care vs Study Specific

Always refer to the protocol; any notes and/or trainings, such as Site Initiation Training; presentations for study-specific guidelines regarding the allowed timing for standard of care imaging that may have already been performed; and whether standard of care scans are acceptable to use for the baseline screening requirement. If the scan was standard of care, the radiologist should read the scan to obtain measurements on all identified lesions. Remember to save

correspondence regarding the identified lesions as source documents.

Tip 3. Know Your Protocol

Refer to the protocol to determine how lesions will be identified and followed. While many protocols use RECIST 1.1, immunotherapy-based clinical trials sometimes use Immune Related Response Criteria (irRECIST),² which takes into account the additional time often needed to demonstrate response using immunotherapy treatments. There are a few differences between the 2 methods, so be sure to know which criteria the protocol uses.

Tip 4. Identify Baseline Lesions

Review lesions with the treating physician and include the lesions on a tracking tool for comparison at subsequent time points. If the treating physician is unsure of what lesions should be followed, consider asking the principal investigator for assistance. Try to use the same terminology as the imaging report to describe the lesions on the tracking tool. Remember: measurable, reproducible, and representative of overall disease burden. Refer to protocol-specific guidelines regarding use of lesions noted with prior radiation, in a surgical field, or areas that have been biopsied, as these lesions may be required to be classified as nontarget lesions.

Tip 5. Communicate Lesion (Target and Nontarget) Information to the Radiologist Ahead of Time

Take time to understand your facility and workflow. Identify a contact in the imaging department to facilitate your requests. When communicating regarding follow-up scans,



include target lesion information in the order and send an email prior to the scan to your contact in the imaging department. Include the location and image slice from previous scans, if known. Request lesions to be measured in 2 dimensions.

Tip 6. Consider Scan Timing

Understand what works best for the patient within protocol parameters. If the patient is not a "morning person," ensure that their appointments are scheduled for the afternoon to promote compliance. Scans should occur before provider visits to allow ample time to analyze and review the results. Consider obtaining scans a few days prior to avoid having to do them the day of the provider visit and/or day 1 of the treatment cycle. In some cases, getting scans after the start of a cycle may be preferred to allow for time to evaluate RECIST response. Remember, scans typically follow set schedules regardless of treatment delay.

Tip 7. Be Proactive

Check for scan results and review the results with the treating physician. This physician may or may not be the principal investigator, and this individual may not be as familiar or

comfortable with the review process. Ideally, RECIST-trained radiologists document the bidimensional measurements, including slice numbers of all target lesions and the presence or absence of nontarget lesions directly within the imaging report. Ask for clarifications or addendums from the radiologist, if necessary. If the treating physician has additional questions, contact the radiologist for clarification. We have found Epic Secure Chat to work well.

Tip 8. Patient Notification

EHR (electronic health record) patient portals release results when completed. Consequently, patients may see their results before the physician or the clinical trials coordinator. When this occurs, patients might call and want to know what the results mean. Understanding this, prepare patients and alleviate fears ahead of time. Have a conversation with patients, assure them that their care team will review the scans, and advise patients that if there is any cause for concern, someone will reach out to them.

Tip 9. Use a Tracking Tool

Make sure the tracking tool lists the protocol information. We use an Excel file that completes the basic RECIST calculation. However, understanding the calculation is critical. Overall response: percent of change is equal to the (current sum of diameters minus baseline sum of diameters) divided by baseline sum of diameters multiplied by 100. Using this formula, a negative number is a decrease and a positive number is an increase in size. Do not forget to include the nadir. If your patient is having a positive response to treatment, the nadir will likely change after each scan. Remember to change the denominator. Also remember that

progressive disease is based on a 20% increase from the nadir and at least a 5-mm increase in sum of the diameters. The tracking tool should be reviewed for accuracy and signed off by the treating physician at each assessment for demonstration of continued physician oversight.

Tip 10. Know Your Resources

These resources include the study protocol; reference articles^{1,3,4}; your team members, physicians, and principal investigators; and ancillary staff in other departments. We are all in this together. Ask questions; it's how we learn. 

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References

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