

AREN03B2 FAQs

We had a patient enrolled and reviewed on AREN03B2 and histology showed that the patient would need to be transferred to a protocol in another disease category (i.e., NBL, RST). Do we need to resubmit radiology materials for the new protocol?

- No, you do not need to resubmit. Please let us know which protocol the patient will be going on. The IROC RI CRAs will coordinate moving the data received, as needed. If there are additional studies required for the new protocol, we would need those.

If we send the radiology materials before the patient is registered, can the review be done?

- No, the registration from COG is required before we can enter the patient into our database. Also, the reviewers directly enter their results into the COG eRDEs, so if the patient doesn't exist there, no results can be entered. We will hold any data received prior to registration until we either have the registration or we hear that it is okay to destroy the data (if data were sent by mistake).

We registered our patient as not intending to enroll on a therapeutic trial. Are we still required to submit the radiology materials?

- As of amendment #5, radiology materials are required for all patients enrolled on AREN03B2.

Our patient has not had a Chest CT, but has had a Chest x-ray. Why will that not be reviewed?

- The Chest CT is the method for review to determine lung metastases in this protocol. An x-ray would not replace the requirement for CT. If the patient is going on to a treatment protocol, this scan is very important in determining if the patient will require lung irradiation or not, and also which treatment protocol the patient will be eligible for.

The radiology reports are not available yet but we have submitted the imaging. Why can't the review be done?

- The radiology reports are important for us to know if the radiology central reviewer is in agreement with the local institution or not. They are also useful in checking to see if we received a complete study (all series of the CT/MR) and if

other prior studies were done for the patient that may be useful (comparison studies mentioned).

The Pre-Operative Abdominal scan for our patient was done at an outside institution. Why can't our repeat scan be used for the review?

- It is important that the radiologist sees the scan that shows the full extent of disease, prior to any biopsy or resection in order to make an accurate evaluation.

We submitted a Chest CT, but we are being asked for a repeat to be submitted. Why?

- Sometimes, a scan may not be evaluable due to movement of the patient during the scan or due to atelectasis. Sometimes, if the Chest CT is done after surgery, there is a cloudy appearance in the lungs that may interfere with determining if there are metastases or not.

Our institution disagrees with the central radiology review. What happens now?

- We try to be proactive about any discrepancies. We have 3 radiologists that perform regular reviews for this protocol. If the 1st reviewer sees that they are in disagreement with the radiology report available, we ask a 2nd reviewer to also look at the case. If both agree, one of them will contact someone at the institution to discuss the case.
- If you receive the Initial Risk Assessment, and your institution disagrees with the radiology portion of the review, please contact IROC RI right away via phone to expedite re-review or explanation.

When will my case be reviewed?

- Data for this protocol is always processed and assigned for review as soon as possible after receipt at IROC RI. Reviews are done within 2 business days of receipt, usually sooner. The reviewers are not located on site at IROC RI. They do the reviews remotely, as soon as possible after they are notified that the case is ready for them. You do not need to ask for expedited review, as all cases on this protocol are treated with the highest priority.

Is an US required?

No, we do need any US for IROC RI review.

Can IROC RI tell me the Risk Assignment for the patient?

IROC RI only handles the radiology reviews for this protocol. Other reviews are also taken into account for the Risk Assignment, which is done by the Study Chair after all relevant information is available.