## Patient Case Review

**Protocol Number:** _____ **CTEP Site Code:**_____ **Patient ID #:** _____

| Category | Major/ Lesser | OK | Not Reviewed | Overall Comments |
|---|---|---|---|---|
| Informed Consent | [ ] | [ ] | [ ] | |
| Eligibility | [ ] | [ ] | [ ] | |
| Treatment | [ ] | [ ] | [ ] | |
| Disease Outcome/Response | [ ] | [ ] | [ ] | |
| Adverse Events | [ ] | [ ] | [ ] | |
| General Data Management Quality | [ ] | [ ] | [ ] | |

## Patient Case -Informed Consent

| Deficiency for Informed Consent | Yes | No | Comments |
|---|---|---|---|
| Consent form document missing | [ ] | [ ] | |
| Consent form document not signed and dated by the patient/study participant | [ ] | [ ] | |
| Translated consent or short form not signed and dated by a non-English speaking patient/study participant | [ ] | [ ] | |
| Consent form not signed by patient prior to study registration/enrollment | [ ] | [ ] | |
| Consent form does not contain all required signatures | [ ] | [ ] | |
| Consent form used was not the current IRB-approved version at the time of patient registration | [ ] | [ ] | |
| Consent form not protocol specific | [ ] | [ ] | |
| Consent form does not include updates or information required by IRB | [ ] | [ ] | |
| Re-consent not obtained as required | [ ] | [ ] | |
| Consent of ancillary/advanced imaging studies not executed properly | [ ] | [ ] | |
| Other deficiencies found for Informed Consent (Note if major or lesser) | [ ] | [ ] | |

## Patient Case - Eligibility

| Deficiency for Eligibility | Yes | No | Comments |
|---|---|---|---|
| Review of documentation available at the time of the audit confirms patient/study participant did not meet all eligibility criteria and/or eligibility requirements were not obtained within the timeframe as specified by the protocol | [ ] | [ ] | |
| Documentation missing; unable to confirm eligibility | [ ] | [ ] | |
| Other deficiencies found for Eligibility<br>(Note if major or lesser) | [ ] | [ ] | |

## Patient Case - Treatment

| Deficiency for Treatment | Yes | No | Comments |
|---|---|---|---|
| Incorrect agent/ treatment/intervention used | [ ] | [ ] | |
| Additional agent/ treatment/intervention used which is not permitted by protocol | [ ] | [ ] | |
| Dose deviations, modifications, or incorrect calculations (error greater than +/- 10%) | [ ] | [ ] | |
| Dose modifications/ treatment interventions not per protocol | [ ] | [ ] | |
| Treatment/intervention incorrect or not administered correctly, incorrectly calculated, or not adequately documented | [ ] | [ ] | |
| Timing and sequencing of treatment/intervention not per protocol | [ ] | [ ] | |
| Unjustified delays in treatment/intervention | [ ] | [ ] | |
| Other deficiencies found for Treatment (Note if major or lesser) | [ ] | [ ] | |

## Patient Case - Disease Outcome/Response

| Deficiency for Disease Outcome/Response | Yes | No | Comments |
|---|---|---|---|
| Inaccurate documentation of initial sites of involvement | [ ] | [ ] | |
| Tumor measurements/ evaluation of status or disease not performed or not documented according to protocol | [ ] | [ ] | |
| Protocol-directed response criteria not followed | [ ] | [ ] | |
| Claimed response (PR, CR, etc.) cannot be verified or auditor could not verify the reported response | [ ] | [ ] | |
| Failure to detect cancer (as in a prevention study) or failure to identify cancer progression | [ ] | [ ] | |
| Other deficiencies found for Disease Outcome/Response (Note if major or lesser) | [ ] | [ ] | |

## Patient Case - Adverse Event

| Deficiency for Adverse Event | Yes | No | Comments |
|---|---|---|---|
| Grades, types, or dates/duration of serious adverse events inaccurately recorded | [ ] | [ ] | |
| Adverse events cannot be substantiated | [ ] | [ ] | |
| Follow-up studies necessary to assess adverse events not performed | [ ] | [ ] | |
| Failure to report or delayed reporting of an adverse event that would require filing an expedited Adverse Event (AE) report or reporting to the Group | [ ] | [ ] | |
| Recurrent under- or over-reporting of adverse events | [ ] | [ ] | |
| Other deficiencies found for Adverse Events (Note if major or lesser) | [ ] | [ ] | |

## Patient Case - General Data Management Quality

| Deficiency for General Data Management Quality | Yes | No | Comments |
|---|---|---|---|
| Recurrent missing documentation in the patient/study participant records | [ ] | [ ] | |
| Protocol-specified laboratory tests not reported or not documented | [ ] | [ ] | |
| Protocol-specified diagnostic studies including baseline assessments not done, not reported or not documented | [ ] | [ ] | |
| Protocol-specified research/advanced imaging studies not done or submitted appropriately | [ ] | [ ] | |
| Frequent data inaccuracies | [ ] | [ ] | |
| Errors in submitted data | [ ] | [ ] | |
| Delinquent data submission (> 6 month delinquency is considered a major deficiency; a 3-6 month delinquency is considered a lesser deficiency) | [ ] | [ ] | |
| Other deficiencies found for General Data Management Quality (Note if major or lesser) | [ ] | [ ] | |